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Consequences of disclosing clinical trial results: Evidence from the food and drug administration amendments act

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Consequences of Disclosing Clinical Trial Results: Evidence from the Food and Drug Administration Amendments Act

Abstract

We examine how the U.S. Food and Drug Administration Amendments Act (FDAAA) of 2007, which requires additional disclosures regarding clinical trial results, impacts information asymmetry between the disclosing pharmaceutical firm and capital market participants, the general public, academics, and practitioners. We document a reduction in information asymmetry in capital markets. We also document an increase in adverse event and product problem complaint reports filed against the pharmaceutical firms to the FDA and a higher number of drug and medical device recalls for affected firms after the FDAAA enactment. Finally, cross-sectional analyses suggest that the increase in FDA complaint reports and recalls after the FDAAA enactment was more prominent in firms with a higher bid-ask spread decrease. Taken together, our results suggest that the FDAAA has some benefits for both investors and consumers.

Keywords: disclosure, information asymmetry, clinical trial, regulation

JEL codes: M41, M48, I18

1. Introduction

Following the Vioxx drug scandal in the United States, where about 38,000 to 63,000 lives were lost in part due to untimely disclosure of clinical trial results, the U.S. Congress passed the Food and Drug Administration Amendments Act (FDAAA) of 2007, requiring pharmaceutical firms to increase their disclosures of clinical trial results.[1] The Act requires firms conducting clinical trials to register them on the ClinicalTrials.gov website, and to publish the clinical trial results within a year of trial completion (Public Law 110-85, 110th Congress).[2] In this paper, we examine the impact of the FDAAA on (1) information asymmetry between the pharmaceutical firm and its investors in capital markets; (2) on the general public, academics, and practitioners who are monitoring these firms through the adverse event and product problem reports filed with FDA and firms' drug and medical device recalls.

Section 801 of the FDAAA requires that all applicable clinical trials starting after September 27, 2007 or ongoing before December 26, 2007 have to be registered and their results disclosed on the ClinicalTrials.gov website. An applicable clinical trial is an interventional clinical investigation of drugs, biological products, genetic treatments, radiation, or devices, post-Phase 1, which falls under the FDA jurisdiction and/or is conducted in part or entirely in the U.S. (e.g., Anderson et al., 2015). This rule applies to any domestic and foreign entity (sponsor) under FDA jurisdiction conducting clinical trials, including, but not limited to, universities, research institutes, and pharmaceutical firms. A single clinical trial can be sponsored by a single, or multiple entities (sponsors).

The major novelty of Section 801 is that it mandates registration and result publication

[1] Researchers started contesting Vioxx results after they were published in 2001 (e.g., Mukherjee et al., 2001; Jüni et al., 2004;). Vioxx was withdrawn from the market in 2004, after causing coronary heart disease in 88,000 to 140,000 patients, from which 38,000 to 63,000 died, according to medical researchers' estimates (Horton, 2004; Graham et al., 2005; Maxwell and Webb, 2005).
[2] See Section 801 of FDAAA and https://clinicaltrials.gov/ct2/manage-recs/fdaaa.

within one year of trial completion (or termination). Completion of a trial is defined as "the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome" (see ClinicalTrials.gov). Civil financial penalties will be imposed if a sponsor (pharmaceutical firms or other research institutions) conducting the trial fails to report their clinical trial results on the ClinicalTrials.gov website; other penalties may involve the withholding federal grant funds. However, compliance with the FDAAA remains weak (Anderson et al., 2015, Zarin et al., 2015).

From a capital market perspective, it is ex ante unclear whether the FDAAA led to more valuable information being shared with investors and the general public. On the one hand, the goal of the FDAAA was to increase the availability and timeliness of information concerning clinical trials,[3] which might be useful to capital market participants to better assess a firm's competitive advantage.[4] On the other hand, it is not strongly enforced. Although some firms choose to disclose all clinical trial results (e.g., Nisen and Rockhold, 2013), others decide to make disclosures on a case-by-case basis. In this low compliance environment, only around 40% of applicable clinical trial results get published on the ClinicalTrials.gov website (e.g., Anderson et al., 2015; Zarin et al., 2015). This finding suggests that only firms for which the benefits of increased disclosure outweigh the costs will increase their provision of information regarding clinical trials.[5] A firm's decision to selectively comply with the disclosure requirement may be driven by two competing explanations with different predictions on the capital market impact of the disclosure. First, a firm has to have ample

[3] According to the ClinicalTrials.gov website, it is a "Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions."
[4] We discussed with an anonymous analyst covering pharmaceutical stocks on Wall Street who told us that the disclosure of clinical trial outcomes constitutes a key source of information in forecasting the firm's future revenues.
[5] See Jovanovich (1982) and Verrecchia (1983) for the theoretical argument.

discretion in choosing the level of detail in its published reports.[6] As such, it is possible that they disclose information that carries virtually no value to capital market participants, either because the report is not precise enough or because the results have already been leaked and hence are also already priced. Assuming that the non-compliance cost with the FDAAA is positive (yet small), a firm could produce non-informative reports. In this case, we should not expect any capital market benefits from these disclosures.[7]

Alternatively, the positive non-compliance costs may explain why some firms commit to always disclosing clinical trial results. In this scenario, the theoretical intuition is that firms would not systematically disclose in the pre-regulation period and the market would not unravel all information possessed by companies due to the proprietary nature of this information (Capkun et al., 2019). However, the incremental monetary (and possibly reputational) non-compliance cost is pushing firms towards more disclosure. Under this scenario, firms would produce and report valuable information to market participants. Overall, the effect of a regulatory intervention towards more disclosure in a low enforcement regime remains an empirical question.

We first examine the potential capital market benefits of increased disclosure induced by Section 801 of the FDAAA. We limit our study to applicable clinical trials and focus on affected pharmaceutical firms around the enactment of the FDAAA in 2007. We analyze the bid-ask spreads of 163 unique pharmaceutical firms whose clinical trial result disclosures are

[6] For more details, see the FDAAA and the ClinicalTrials.gov website for examples of disclosures. For instance, detailed information disclosed for study NCT00729326, which tracked the change history of information level and trial results disclosed over time, is found at https://clinicaltrials.gov/ct2/history/NCT00729326?A=1&B=9&C=Side-by-Side#StudyPageTop. This view provides a side-by-side comparison between the first registration without results and the latest version with results. Edits or deletions are displayed in red and additions are displayed in green. This view shows the direct evidence that there is a significant amount of information that is disclosed once the results are published on the ClinicalTrials.gov website.

[7] This effect may be amplified by the disclosure forum. Indeed, the disclosed information is published on a governmental agency website, making it less clear whether investors will process this information efficiently. In line with this argument, Christensen et al. (2017) find stronger capital market effects when information about mine safety records is additionally disclosed in financial reports rather than exclusively on a governmental platform.

affected by the FDAAA over the sixteen-quarter (four-year) period centered on its implementation in September 2007. We use an empirical model reminiscent of a difference-in-differences (DiD) design where we benchmark the change in the bid-ask spread of our pharmaceutical firms to that of various control groups, including other firms in the same industry, whose clinical trials results were not required to be disclosed under FDAAA, as well as the matched nearest neighbor pair firms from other industries. Our results reveal a significant average decrease of 59.71 (46.71) basis points in bid-ask spreads compared with other firms in the same industry (compared with the matched nearest neighbor pair firms from other industries) after the FDAAA. We find no supportive evidence that the change in information asymmetry (measured by the bid-ask spread) in capital markets precedes the change in disclosure regulation for pharmaceutical firms relative to various benchmark control groups. Our results are further confirmed when we limit the sample to only those firms that indeed disclose clinical trial results in the post-FDAAA period. They are also confirmed when we limit the sample to those firms that disclosed their clinical trial results in a timely manner (before the one-year deadline).

Next, we investigate the regulatory consequences outside capital markets by examining the monitoring role of the general public, academics, and practitioners on pharmaceutical firms. In particular, we focus on 1) the change in public and academic attention to clinical trials and FDAAA related topics, as measured by a Google Trends web search score of clinical trial-related keywords and PubMed.gov medical science research publication topics; 2) the change of adverse event and product problem reports (complaint event records) filed by the general public, academics, and practitioners to the FDA against pharmaceutical firms; and 3) the change in the number of drug/medical device recalls filed by pharmaceutical firms and the FDA. If, indeed there was a reduction in asymmetry of information between insiders and outsiders, it would improve the ability of outsiders to

scrutinize and monitor the firm, leading to greater public and academic attention, potentially more public complaint reports, and FDA recalls after the FDAAA. In other words, releasing results on clinical trials allows academics and practitioners to cross-check those results with their own findings and real-life cases. Arguably, this should lead to a higher level of public attention, as well as a greater number of public complaints reports and recalls.

We first establish that a Google Trends web search of FDAAA clinical trial-related keywords "clinicaltrials.gov" and "FDAAA" and the number of related medical publications on PubMed.gov increases right after the implementation of the FDAAA.[8] This indicates that outsiders perceived the additional information disclosed on ClinicalTrials.gov as potentially valuable. Furthermore, we collect data on medical device reports (MDRs) — adverse event and product problem reports filed by the general public, academics, and practitioners — from the FDA Manufacturer and User Facility Device Experience (MAUDE) database and drug and medical device recalls data on the FDA website (fda.gov). We find a sharp increase in adverse events, product problem reports and recalls after the FDAAA, in number, scaled by the number of clinical trials and by firm. MAUDE recorded MDR complaint events (including both adverse events and product problems) increase from 17,558 three years before the FDAAA to 74,453 three years after the FDAAA, increased by 4.24 times. The total number of recalls (including both drug and medical device recalls) increased from 113 three years before the FDAAA to 482 three years after the FDAAA, increased by 4.27 times. Scaled by the number of completed clinical trials, recalls increase from 19.32% to 35.49% during the same period. After controlling for firm characteristics, the probability for a pharmaceutical firm to receive an MDR complaint report in the MAUDE database for either an adverse event or a product problem increased by 2.82% per quarter in the post-FDAAA

[8] Regarding the outcome of the FDAAA on scientific research, research papers with citations of the keyword "clinicaltrials.gov" increase more than that of "clinical trials" in citations, which serves as a benchmark for our comparison.

period. Accordingly, the probability for a pharmaceutical firm to recall a drug or medical device increased by 2.17% per quarter.[9] A clear pitfall of our approach in this second set of tests is that since we now focus on FDAAA related topics, we lose our ability to use a benchmark group but focus on time series differences instead. However, collectively our evidence suggests that scrutiny on clinical trials from customers/general public and scientific researchers increases after the FDAAA.

Finally, we examine whether firms that experience more public complaints and recalls also experience a larger decrease in information asymmetry in capital markets. This test is motivated by the events surrounding the Vioxx recall in 2004. In this emblematic case, once the results of clinical trials were made public, researchers started analyzing the data and conducting their own trials, which ultimately led to the public complaint and recall of the drug. We conjecture that earlier disclosure of clinical trials will allow for a better interaction between the general public and researchers that will ascertain the viability of the drugs and public market participants that are pricing securities. Such cross-checking of the drug development process should indeed lead to better estimation of future revenues by pharmaceutical firms. In line with this prediction, our cross-sectional tests reveal that firms that experience more public complaints and recalls are also the ones experiencing a more pronounced decrease in bid-ask spread after the FDAAA.

Overall, our results demonstrate that both investors and the general public benefitted from the FDAAA. Our findings contribute to several streams of the disclosure literature. First, low firm compliance with the FDAAA yields a setting with both mandatory and voluntary disclosure features. Our results add to the literature on the impact of mandatory disclosure with imperfect compliance, but also provide evidence to the voluntary disclosure literature.

[9] Given that the consequences (especially the effects of the FDAAA on recalls) take longer to be known than the market effects, the summary statistics of consequences interpreted here is based on a longer balanced 24-quarter period with 12 quarters in each pre- and post-period.

Related studies examine other mandatory and voluntary disclosure settings with varying degrees of disclosure requirements and compliance, and report mixed evidence on the relation between regulations and information asymmetry [see Leuz and Verrecchia (2000), Hail (2002), Hail and Leuz (2006), Christensen et al. (2013), and Christensen et al. (2015) for international evidence and IFRS adoption; see Eleswarapu et al. (2004), Koch et al. (2013), and Bushee et al. (2017) for Regulation FD; see Jain et al. (2008) and Coates and Srinivasan (2014) for the SOX regulation; and Beyer et al. (2010), and Leuz and Wysocki (2016) for review of disclosure literature].

Second, our paper contributes to the literature on the consequences of disclosure and reduced information asymmetry. These studies find that enhanced disclosure has a positive effect on various outcomes, including food hygiene (Jin and Leslie, 2003), corporate investment (Biddle et al., 2009; Shroff et al., 2014), social responsibility in the mining industry (Christensen et al., 2017), and environmental issues (Bennear and Olmstead, 2008). We add to this literature by showing that increased disclosure regarding clinical trial results leads to capital market benefits and helps stakeholders to analyze the drugs/devices, thus leads to more FDA MDR complaint reports and then the firm may recall the product for safety reasons. In this sense, our findings suggest that disclosure of clinical trial results might help to discipline product market behavior.

Finally, we also contribute to the literature on the disclosures of clinical trial results. Anderson et al. (2015) develop an algorithm to identify clinical trials that were likely to be subject to FDAAA provisions. They document that despite legal obligations to disclose findings promptly, a significant number of firms do not report results to the FDA in a timely fashion, if at all. Williams et al. (2015) concentrate on clinical trials that were terminated and investigate the extent to which their data were disseminated. Other studies investigate a particular drug or device. For example, Jüni et al. (2004) study Vioxx and conclude that data

from clinical trials should have led to an earlier withdrawal of the drug. We take a different approach and provided, to the best of our knowledge, the first examination of both the capital market benefits of clinical trial result disclosures and their association with product scrutiny. More recently, a contemporaneous paper by Hsu et al. (2019) finds that there are more suspensions of new clinical trials after the passage of FDAAA due to the improved transparency on drug development.[10]

The rest of the paper is organized as follows. In Section 2, we provide an overview of the institutional background. In Section 3, we describe the data and sample selection process. In Sections 4 through 6, we present the research design and identification strategy, and discuss the results and robustness. Concluding remarks are in Section 7.

2. Institutional Background on Section 801 of FDAAA and ClinicalTrials.gov

The pharmaceutical industry is a crucial sector to human life and health, and it is also an important sector that accounts for one-fifth of the economy in the U.S. (Thakor and Lo, 2015). Thus, a number of changes to clinical trial reporting have been attempted, proposed, and discussed. For example, the Food and Drug Administration Modernization Act (FDAMA) of 1997 required all clinical trials to be registered with the FDA, and on ClinicalTrials.gov launched in 2000, which gave firms a platform to post their studies. However, it was not until the Vioxx scandal, which cost tens of thousands of lives due to untimely disclosure of clinical trial results, that the U.S. Congress passed the Food and Drugs Administration Amendments Act (FDAAA, Public Law 110-85, 110th Congress) in 2007, which requires pharmaceutical firms to disclose the results of their applicable clinical trials[11] on ClinicalTrials.gov. For a

[10] Note that the change in composition of clinical trials towards higher quality drugs documented in Hsu et al. (2019) reduces our chances to document an increased scrutiny through recalls.

[11] An applicable clinical trial is an interventional clinical investigation of drugs, biological products, genetic treatments, radiation, or devices, post-Phase 1, which falls under the FDA jurisdiction and/or is conducted in part or entirely in the U.S. (e.g., Anderson et al., 2015). This rule applies to any domestic or foreign entity (sponsor),

review of how the regulation of clinical trials disclosures evolved over time, see Zarin et al. (2015).

More precisely, Section 801 of the FDAAA also specifies and requires that all applicable clinical trials starting after September 27, 2007 or ongoing before December 26, 2007 had to be registered first on ClinicalTrials.gov and their results should be published within one year after the completion of the clinical trial. Completion of a trial is defined as "the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome" (see ClinicalTrials.gov).

ClinicalTrials.gov is a publicly available government website initiated on February 29, 2000 that "provides patients, their family members, medical researchers and health care professionals easy access to information about clinical trial studies on a range of diseases and conditions" (see ClinicalTrials.gov). The information on the website is provided and updated by the sponsor or principal investigator of a clinical trial. The website is maintained by the U.S. National Library of Medicine (NLM) at the National Institutes of Health (NIH). ClinicalTrials.gov contains the registration information of clinical trials, but it was not until FDAAA Section 801 that there was a legal requirement for the registration and disclosure of clinical trial results.

The requirement to disclose clinical trial results is enforced according to the characteristics of the clinical trial. Using this setting, we can identify the clinical trials affected by the FDAAA whose results require disclosure. Then we identify the treatment group of firms that have those trials, and we define our control group of firms that do not have any affected trials. Using this identification strategy at the clinical trial level, we can identify a control group firms that are closely linked to the treatment group firms in the same industry, but do not have clinical trials subject to the FDAAA disclosure requirement. In an alternative

including e.g., universities, research institutes, and pharmaceutical firms. A single clinical trial can be sponsored by a single or multiple entities (sponsors).

identification strategy, we identify a matched and balanced control group of firms outside the drugs industry to assess our treatment effect using a cross-industry approach. Our within and across industries identification strategy enhance the internal and construct validity of our findings.

3. Sample Selection and Data Employed

3.1 Sample selection

We follow Anderson et al. (2015) and Capkun et al. (2019) to identify the treatment firms, those pharmaceutical firms with clinical trials that are subject to the FDAAA requirements. For that purpose, we use the Aggregate Analysis of ClinicalTrails.gov (AACT) database collected from the Clinical Trials Transformation Initiative (CTTI) website.[12] To capture firms impacted by FDAAA, we start with all clinical trials for the 2007-2014 period,[13] for which there is complete information on sponsors, registered countries, authorities, intervention type, and recruitment status. We only include the clinical trials that are funded or sponsored by listed firms or their subsidiaries. We exclude trials before Phase 2, as well as those that have not been completed or terminated, because they are not subject to FDAAA disclosure requirements. The remaining clinical trials are subject to FDAAA result disclosures, and we identify firms with at least one clinical trial subject to FDAAA disclosure requirements. We further restrict this sample to firms with the data necessary to conduct our tests. More specifically, we use Compustat and the Center for Research in Securities Prices (CRSP) to obtain financial data. We restrict our sample to firms with complete data for all our

[12] CTTI processes data which they obtain from the ClinicalTrials.gov website.

[13] Even though our sample period extends only to two years after regulation change (until 2009), we choose to use a longer (seven years) period after implementation of the FDAAA to identify our treatment firms. We do this to make sure that we capture not only firms that had Phase 2 and later-stage clinical trials to which the FDAAA applies, but also their competitors, which are firms in our sample period that had earlier stage or pre-trial R&D projects, and only later appear on the ClinicalTrials.gov website once they reach Phase 2. Broadly, a longer time period ensures that we capture all "active" pharmaceutical firms regardless of whether they had Phase 2 or later projects during our sample period.

variables. Our sample period runs from 8 quarters (2 years) before to 8 quarters (2 years) after the implementation of the FDAAA in September 2007.[14] This yields a treatment sample that consists of 163 unique pharmaceutical firms, whose clinical trial results are subject to disclosure under the FDAAA.

We use this treatment sample of 163 unique firms throughout our tests for both capital market outcomes and real consequences of the FDAAA. In our capital market tests, we compare this treatment group with two different control groups. A first control group is composed of 63 firms from the same industry (SIC code 283 - Drugs) that are not subject to FDAAA disclosure requirements. In this test, we thus use data for 226 firms over 16 quarters, yielding 3,616 firm-quarter observations. An alternative control group is composed of a balanced matched sample of 5,184 firm-quarter observations over the 16-quarter window from 324 U.S. firms, in which 162 pharmaceutical firms are subject to FDAAA (treatment) and 162 firms are the matched nearest neighbor firms outside the drugs industry (SIC code different from 283) (control). The matching procedure is used to identify the nearest neighbor paired firm based on total assets and R&D investment in the last quarter before the implementation of FDAAA. This test allows us to compare the impact of the FDAAA for treatment firms relative to control firms of similar size and R&D investment across industries.[15]

3.2. Google Trends

To obtain data on public interest in FDAAA and the ClinicalTrials.gov website, we hand-collect monthly Google Trends data for the search terms "clinicaltrials.gov" and “FDAAA” for the period surrounding September 2007, from September 2005 until September

[14] Following the literature, we exclude from our analysis the fiscal quarter in which the FDAAA was implemented to reduce the measurement noise in that quarter introduced by the regulation change.
[15] After matching on total assets and R&D/total assets in the last quarter before the regulation change with outside the pharmaceutical industry, we get 162 pairs of perfectly balanced firms; only one pharmaceutical firm does not obtain a satisfactory match.

2009. Google data show scaled search volume, with the values ranging from 0 to 100. The data are scaled by the highest search volume over the search (our sample) period. A value of 100 thus represents the peak popularity for the term over the search time period, and a value of 50 means that the term is half as popular. We also collect Google Trends data for the search term "clinical trials" in order to use it as a benchmark against the change in public interest in the FDAAA and ClinicalTrials.gov. For each search term, we obtain 48 monthly observations from September 2005 to September 2009.[16]

3.3. PubMed

We use the PubMed.gov database to measure the interest of medical researchers in the ClinicalTrials.gov website. PubMed is a search engine of references and abstracts of research articles maintained by the National Center for Biotechnology Information at the U.S. National Library of Medicine under the direction of the National Institutes of Health (NIH). PubMed comprises more than 30 million citations for biomedical literature from the Medical Literature Analysis and Retrieval System Online (MEDLINE), life science journals, and online books.

Similar to the hand collection procedure we use for the Google search database, we hand collect the monthly number of medical research publications containing the term "clinicaltrials.gov". We also collect the same data for "clinical trials" which serves as a benchmark. We calculate the trend score the same way as for the Google Trend web search, by scaling the search frequency with the highest monthly search frequency over the search period. A value of 100 thus represents the peak for the number of publications containing the search term. We obtain 48 monthly observations for each search term from September 2005

[16] Similar to Footnote 14, in the regression model we drop the month of September 2007 when the regulation change happened to exclude the noise during that month. However, we still show the month of September 2007 in Figure 2 (Panel A-C) for presentation purposes.

to September 2009.[17]

3.4. FDA MAUDE database and recalls

We use the FDA's Manufacturer and User Facility Device Experience Database (MAUDE) and the FDA website to collect data on reports of adverse events, product problems, and recalls of drugs and medical devices. Each year, the FDA receives hundreds of thousands of medical device reports (MDRs). The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to the risk-benefit assessments of these products. MAUDE stores the MDRs by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters, such as health care professionals, patients, and consumers.[18]

The FDA also provides a list of recall announcements gathered from press releases and other public sources for FDA-regulated products. The list contains recall announcements of drugs and medical devices submitted by the firms themselves or initiated by the FDA. This information is publicly available on FDA website.[19]

We hand-collect data on 55,177 adverse event and 97,343 product problem MDR reports from FDA MAUDE database, as well as 888 drug and medical device recalls from the FDA website for our treatment sample of 163 pharmaceutical firms over the 16-quarter sample period. This dataset serves the investigation in the main tests of real consequences of the FDAAA, which yields 2,608 firm-quarter observations for FDA MDRs and recalls.[20]

[17] We smooth the number of citations for every January collected from PubMed by taking the average number of the two adjacent months (i.e., December and February), because citation numbers reported in January in PubMed are outliers, as by default the number in January automatically includes all the publications published throughout the current year without specific information of the month.
[18] For further information, see https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
[19] See https://www.fda.gov/safety/recalls/.
[20] Given that the consequences (especially the effects of the FDAAA on recalls) take longer to be known than the market effects, we also perform an additional test on the consequences over a longer balanced 24-quarter period with 12 quarters in each pre- and post-period. For that test, we hand-collect 89,767 adverse event and 160,895 product problem MDR reports, as well as 1,483 recalls. This yields 3,408 firm-quarter observations.

4. Capital Market Tests

4.1. Baseline model

We perform multivariate regressions to investigate the capital market impact of the FDAAA and focus on liquidity as proxy for a change in information asymmetry. Our empirical strategy relies on the prediction that firms whose clinical trials are subject to the FDAAA disclosure requirement provide more (or no) information to the market than other non-affected firms. We use a model reminiscent of a difference-in-differences framework, where firms with no applicable clinical trials (in the pharmaceutical industry or other industries) are the control group. We estimate the following regression model where the unit of analysis is firm-quarter.

Model 1:

$$Spread\ 100_{i,t} = \beta_0 + \beta_1 \bullet Pharma\ X\ Post + \sum \lambda_n \cdot Controls_{i,t-1} + Firm\ Fixed\ Effects + Year\text{-}Quarter\ Fixed\ Effects + \varepsilon_{i,t} \quad (1)$$

In Model 1, our baseline model, *i* denotes the firm and *t* denotes the quarter. We use a firm's bid-ask spread, *Spread 100*, as a measure of market liquidity, which is a proxy for a stock's information asymmetry in financial markets. We measure the daily bid-ask spread as the difference between the quoted closing ask and bid price, scaled by the closing daily CRSP price. We then calculate the average daily bid-ask spread in the current quarter and multiply it by 100 to determine the basis point(s), labelled *Spread 100* (Balakrishnan et al., 2014).

Our treatment group is composed of 163 unique pharmaceutical firms whose clinical trials are subject to registration on ClinicalTrials.gov required under the FDAAA. As discussed in the previous section, we use two alternative control groups (1) a group of unaffected firms within the drugs industry (SIC code 283) that presumably are exposed to the same economic trends, and (2) a group of matched firms from other industries but with similar size and R&D spending. In Model 1, *Pharma* is a binary variable equal to 1 if the firm

is in the treatment group, and equal to zero in the control group.

Post is a binary variable equal to 1 if the data date is after September 27, 2007, the date when the FDAAA took effect, and zero otherwise. The variable *Post* is omitted from the estimation as we have year-quarter fixed effects in the specification. In addition, the variable *Pharma* is subsumed by the firm fixed effects. Our variable of interest is the interaction term *Pharma X Post.*

In Model 1, we control for firm-level characteristics that impact the firm's market liquidity. We control for firm size (*Ln Market Cap*), growth and financing needs and constraints (*Book-to-Market*), financing structure and financing need (*Book Leverage*), firm performance (*ROA* and *Loss*), daily average stock return in the lagged quarter (*Quarterly Stock Return*), stock return volatility (*Stock Return Volatility*), and extraordinary events (*Special Items*). This list of covariates is derived from Samuels (2016). Firm- and year-quarter fixed effects are included to rule out other unobserved confounding effects at the firm and macro levels. In robustness tests, we also add quarter-state fixed effects to rule out unobserved confounding effects at the quarter-state level. All continuous variables are winsorized at the 1st and 99th percentiles. Standard errors are clustered at the SIC 3-digit industry level to adjust any unobserved components in the error term that may be correlated within the pharmaceutical affected industry. See the Appendix for variable definitions.

4.2. Descriptive statistics

Table 1 provides the descriptive statistics. In Panel A, we present the descriptive statistics for our pooled sample of treatment and control firms within the drug industry. Firms subject to the FDAAA have a representation of 72.1%, while 34.6% (22.2%) of firms submit results on the ClinicalTrials.gov website (on time) after the FDAAA. In Panel B, we report the descriptive statistics for our pooled sample of treatment firms and matched control firms from other industries. In Panel C, we provide summary statistics on the consequences of

MDR reports and recalls for the pharmaceutical firms subject to the FDAAA.

Table 2 provides the results of a univariate comparison between the treatment group of pharmaceutical firms and the two control groups in the last fiscal quarter before the implementation of the FDAAA. In Panel A, the control group is the rest of the drugs industry firms (SIC code 283). The results indicate that the treatment and control firms differ on some observable dimensions (e.g., *Ln Market Cap* and *Book-to-Market*). Similarly, the results in Panel B indicate that treatment firms from the pharmaceutical industry and control firms from other industries, while matched on size and R&D expenses, also exhibit some differences in other observable characteristics (e.g., *Book Leverage*, *ROA* and *Loss*). Overall, we acknowledge that our two control groups remain statistically different from the treatment group to certain extent, and we managed to identify those observed control variables to construct the baseline model.

4.3. Baseline regression results

The results of Model 1 are shown in Table 3. In columns (1) and (2), we report our estimates using the rest of the drugs firms as the control group, while in columns (3) and (4), the matched pair firms outside the drugs industry are the control group. Specifications are different in columns (1) and (3) where no control variables are included in the specification, while in columns (2) and (4), firm-level control variables are included in the specification. The coefficients of our variable of interest, *Pharma X Post*, is negative and significant at the 1% level in all the specifications, suggesting that the FDAAA decreases the bid-ask spread from the pre-period to the post-period for firms in the treatment group relative to those in the control group.

Furthermore, the signs of the control variables are generally consistent with the literature. For instance, larger firms with higher leverage and lower stock return volatility tend to have lower bid-ask spreads (e.g., Leuz and Verrecchia, 2000, Roll, 1984). Taken together,

these findings are consistent with our argument that the clinical trial disclosures due to the FDAAA leads to a decrease of information asymmetry.

4.4. Pharmaceutical firms alternative treatment group

We estimate our regression of Model 1 using refined pharmaceutical firms in the treatment group. We specifically identify those pharmaceutical firms that were subject to the FDAAA and submitted their clinical trial results (*Pharma Submission*), and those that submitted their results early in a timely manner before the due date (*Pharma Early*). We perform these two identification strategies using characteristics at the clinical trial level.

The results in Table 4 are from regressions using *Pharma Submission* and *Pharma Early* with refined pharmaceutical firms in the treatment groups. *Pharma Submission* is a binary variable equal to 1 if the pharmaceutical firm's clinical trial results were subject to the FDAAA disclosure requirement, and that the firm disclosed at least one of its clinical trial results; zero otherwise. *Pharma Early* is a binary variable, equal to 1, if the pharmaceutical firm's clinical trial results were subject to FDAAA disclosure requirement, and that the firm disclosed at least one of its clinical trial results on time (within 365 days of the completion); zero otherwise. Firm-level control variables are the same as those in the baseline Model 1.

In columns (1) through (4) in Table 4, the coefficients of the interaction terms *Pharma Submission X Post* and *Pharma Early X Post* are negative and significant at the 1% or 5% level for all the four specifications, suggesting that the effect of the FDAAA on market liquidity also holds for pharmaceutical firms that indeed submit clinical trial results and those that also submit the results on time. These findings further increase the internal and construct validity of the findings for Model 1.

4.5. Dynamic analysis

We perform a parallel trend analysis to check whether our documented effect preceded the FDAAA disclosure requirement. In Panel A of Table 5, the results are reported using a

breakdown of our time variable by fiscal quarter, where *Pre FQn* is defined as the n^{th} fiscal quarter in the pre-period before the quarter when the FDAAA was enacted on September 27, 2007. Consistently, *Post FQn* is defined as the n^{th} fiscal quarter in the post-period after the quarter when the FDAAA was enacted. In Panel B, the results are presented by fiscal year, where *Pre FYn* and *Post FYn* are defined similarly with fiscal year as interval for the time frequency. The variables of interest are those interaction terms between *Pharma* and *Post FQn*, as well as those between *Pharma* and *Post FYn*.[21] Firm-level control variables are the same as those in the baseline Model 1. Year-quarter fixed effects and firm fixed effects are also included in the specifications. The control group in the regression for column (1) for both panels is the rest of the drugs firms, while control group in the regression for column (2) is the matched pair firms outside the drugs industry.

The results in Panel A of Table 5 show that across all the specifications, the coefficients for the interaction term for the quarterly trend is only negatively and statistically significant in the post-period on *Pharma X Post FQn* and not in the pre-period on *Pharma X Pre FQn*, suggesting that the reduced information asymmetry is unlikely to be driven by other confounding events before the FDAAA. The results in Panel B also confirm our parallel trend assumption with year intervals. For an additional support in favor of not violating the parallel trend assumption, we plot our results in Figure 1 (Panel A and B). Overall, our results tend to suggest that the reduction in information asymmetry in capital markets is due to the FDAAA.

4.6. Robustness tests

We perform several robustness tests to validate our results. We vary the sample period of the liquidity baseline tests for these tests. In Panel A of Table 6, we find significant results for the 24-, 8-, 6-, and 4-quarter windows of the sample period centered on the FDAAA in September 2007. In addition to firm fixed effects, we also replace year-quarter fixed effects

[21] The indicators for *Pharma X Pre FQ8* and *Pharma X Pre FY2* are omitted and serve as benchmark.

by quarter-state fixed effects to rule out unobserved confounding effects at the quarter-state level. Our results in columns (1) and (2) in Panel B of Table 6 are robust to this augmentation of fixed effects. Finally, our results are also robust in column (3) when we use the rest of the Compustat firms as control group in the regression, which helps us further enhance the external validity of our findings.

5. Public and Academic Attention to FDAAA and Clinical Trials Disclosures

In this section we investigate the impact of the FDAAA on consumers, researchers, and medical professionals' attention and their monitoring role on clinical trial disclosures.

5.1. FDAAA and public attention

First, we examine whether the FDAAA has an impact on the public and researchers' attention to the FDAAA and clinical trial results disclosures. We conduct two tests to see whether there is a general increase in Google Trends and PubMed searches of the keywords "FDAAA" and "clinicaltrials.gov" after the passage of the FDAAA. These measures are defined in Section 3.

In Figure 2, Panel A, we present monthly trend analysis results from September 2005 to September 2009 about the Google Trends web search score of the keyword terms "FDAAA" and "clinicaltrials.gov" (shown as solid line). The Google score represents search interest relative to the value of 100, which is the peak popularity for the term during this period; a value of 50 means that the term is half as popular. There is a sharp increase in the Google search score for "FDAAA" after September 2007 when FDAAA was enacted, although trend of "clinicaltrials.gov" gradually increases over time after September 2008 when the earliest disclosure of clinical trial results subject to the FDAAA began. Panel B provides falsification test results using the search trend of a broader and more general keyword "clinical trial" (shown as dashed line), which serves as benchmark; this trend

actually decreases, while the search trend of "clinicaltrials.gov" actually increases. Overall, the results in Panels A and B in Figure 2 confirm that there is a sharp increase in public attention to the FDAAA and ClinicalTrials.gov immediately after the implementation of FDAAA, suggesting an increase in public monitoring of pharmaceutical firms' clinical trials.

In addition, we use multivariate tests to examine this monitoring trend. The results are in Panel A of Table 7. We have 48 monthly observations for each keyword from September 2005 to September 2009 (excluding September 2007). Dependent variable *Ln Google "clinicaltrials.gov" US* in column (1) represents the monthly Google search of the keyword "clinicaltrials.gov" (*Google "clinicaltrials.gov" US*) in the log form. Dependent variable *Ln Google "FDAAA" US* in column (2) shows the log form of the monthly Google search of the keyword "FDAAA" (*Google "FDAAA" US*). In addition, we create two other relative measures for the Google search trend. The first one, *Google "clinicaltrials.gov"/"clinical trials" US*, the dependent variable shown in column (3), is the ratio of *Google "clinicaltrials.gov" US* scaled by *Google "clinical trials" US* (the Google search trend of a general term "clinical trials" as benchmark). The other one in the independent variable, *Google clinicaltrials.gov*, is a binary variable equal to 1, if the Google trends web search keyword is "clinicaltrials.gov", zero if the keyword is "clinical trials". Compared with different benchmarks, the results in Panel A confirm the findings of the univariate results in Panels A and B in Figure 2.[22] In conclusion, we find that there is a significant increase in the keywords "clinicaltrials.gov" and "FDAAA" after the implementation of the FDAAA, which suggests an increase in public attention to the FDAAA and an increase in public's monitoring of clinical trials.

In addition, we investigate the aftereffects of the FDAAA in the academic community

[22] The results in columns (1) and (2) show the increasing trend of the keywords "clinicaltrials.gov" and "FDAAA" after the adoption of the FDAAA in September 2007, while columns (3) and (4) show that a keyword search of "clinicaltrials.gov" in Google increases more than keyword search of "clinical trials" (as benchmark) after the FDAAA.

using the citation of "clinicaltrials.gov" in medical research extracted from PubMed. Panel C in Figure 2 presents the results of our monthly trend analysis of research publications from September 2005 to September 2009. The trend in research papers citing "clinicaltrials.gov" (shown as solid line) increases significantly after the FDAAA against the benchmark keyword term "clinical trials" (shown as dashed line). Similar multivariate results are reported in Panel B of Table 7.[23] Both findings confirm that there is an increase in academic attention to ClinicalTrials.gov in terms of the number of related publications after the implementation of the FDAAA. This finding suggests an increase in the monitoring role of clinical trials from the academic community.

5.2. Consequences of FDAAA on the general public

In this subsection, we investigate the impact of the FDAAA on the general public. Specifically, we use regression models on MDR reports (including both adverse events and product problems) and recalls to investigate the consequences of clinical trial result disclosures.

5.2.1. Research design

We focus on the 163 pharmaceutical firms in our initial treatment group since they are affected by the FDAAA. We focus on the 8 quarters before and 8 quarters after the implementation of the FDAAA. We present our specification in Model 2.

Model 2:

$$Consequences = \beta_0 + \beta_1 \bullet Post + \sum \lambda n \bullet Controls_{i,t-1} + Firm\ Fixed\ Effects + \varepsilon_{i,t}. \quad (2)$$

In Model 2, *Consequences* includes different measures of the consequences of the

[23] The results in columns (1) and (2) show the increasing trend of the research topic related to both "clinicaltrials.gov" and "clinical trials" in the PubMed research database after the adoption of the FDAAA in September 2007, while columns (3) and (4) show that research topic related to "clinicaltrials.gov" in PubMed increases more than that of "clinical trials" (as benchmark) after the FDAAA.

FDAAA, such as *FDA MAUDE*, *Ln Total FDA MAUDE*, *Adverse Event*, *Ln Total Adverse Event*, *Product Problem*, *Ln Total Product Problem*, *Recall*, and *Ln Total Recall*. *FDA MAUDE* is a binary variable, equal to 1, if there is an adverse event or product problem MDR report filed against the firm by reporters to the FDA recorded in MAUDE database during the fiscal quarter; zero otherwise. *Ln Total FDA MAUDE* is the natural logarithm form of 1 plus the total number of adverse event or product problem MDR reports filed against the firm to the FDA recorded in MAUDE database during the fiscal quarter. *Adverse Event* is a binary variable, equal to 1, if there is an adverse event MDR report filed against the firm to the FDA recorded in MAUDE database during the fiscal quarter; zero otherwise. *Ln Total Adverse Event* is the natural logarithm form of 1 plus the total number of adverse event MDR reports filed against the firm to the FDA recorded in MAUDE database during the fiscal quarter. *Product Problem* is a binary variable, equal to 1, if there is a product problem MDR report filed against the to the FDA recorded in MAUDE database during the fiscal quarter; zero otherwise. *Ln Total Product Problem* is the natural logarithm form of 1 plus the total number of product problem MDR reports filed against the firm to the FDA recorded in MAUDE database during the fiscal quarter. *Recall* is a binary variable, equal to 1, if the firm submits a drug or medical device recall recorded in FDA database during the fiscal quarter; zero otherwise. *Ln Total Recall* is the natural logarithm form of 1 plus the total number of drug and medical device recalls filed to FDA database during the fiscal quarter.

Given that this is a time series test, *Post* is our variable of interest and we predict it to be positive if the FDAAA had an impact on firms' recall events. All the control variables are defined the same as those for Model 1. Firm fixed effects are included in the model, and the standard errors are clustered at the firm level. Due to the absence of FDA MDR reports in MAUDE database for drug and medical device recalls in industries outside the pharmaceutical industry, the consequences test remains ultimately a time series test without a

comparable control group. As a result, this test will remain non-identified and rely on within-firm changes for treatment firms over time that coincides with the FDAAA.

5.2.2. Summary statistics and results

In Table 8, we track the evolution of clinical trials, FDA MDR reports recorded in the MAUDE database, and recalls by fiscal year from three years before the FDAAA to three years after. All of these numbers increase over time. Completed clinical trials also increase over time, with 585 trials in the three years before the FDAAA to 1,358 trials three years after it. The peak number of completions takes place in the second year after the FDAAA with 1,466 trials. The total number of MDR reports (including adverse events and product problems) in MAUDE database increases from 17,558 to 74,453 over this period; the total of drug and medical device recalls increases from 113 to 482. Scaled by the number of completed clinical trials, recalls increase from 19.32% to 35.49% during the same period. However, the clinical trial result disclosures only start in 2008, which is one year after the implementation of the FDAAA.

The results in Panel A of Table 9 show that, within pharmaceutical firms, the likelihood of FDA MDR reports and adverse event reports per quarter increases after the FDAAA. In addition, the number of FDA MAUDE reports, and adverse event and product problem reports all increase in the aftermath of FDAAA after controlling for firm-level characteristics. This suggests that the FDAAA disclosure requirement of applicable clinical trial results also had affected the scrutiny of the general public. Specifically, the probability of an FDA MAUDE complaint report (adverse event report) increased by 2.13% (1.82%) per quarter in the post-regulation change period. However, the recall usually happens after the receipt of abundant FDA MAUDE reports, which takes longer time to be effective. The consequences of the FDAAA on product recalls are not significant in the short 16-quarter window, which could be due to the delayed effect of recalls. As a result, we extend the

window and perform our tests for a 24-quarter window, where we find significant results for the effect of the FDAAA on recalls.

Panel B of Table 9 shows the results for the 24-quarter window, 12 quarters before and after the FDAAA for the consequences tests in Model 2. The coefficients for the recall tests (likelihood and the number of recalls) become significant at the 5% or 10% level, which suggests that there is a recall delay effect in the later period. Furthermore, Figure 3 shows precisely the untabulated results about the effect of FDAAA on recalls by fiscal quarter and year in the longer 24-quarter window. This figure shows that the increase of recalls happens in the 11^{th} quarter after the FDAAA. To further validate our prediction related to the delayed effect of recalls after FDA MAUDE reports, in untabulated results we find that after controlling for other firm characteristics, recalls are positively and significantly associated with the lagged (1 quarter or 4 quarters) FDA MAUDE complaint reports, showing that recalls takes longer time to be effective after the increase in the number of lagged FDA MAUDE complaint reports.

6. Joint Effects of the FDAAA and its Associated Consequences on Liquidity

6.1. Research design

In this subsection, we combine our two previous analyses and test whether firms that experience more public complaints (MDR reports in MAUDE database) and recalls after the FDAAA also experience a larger decrease in information asymmetry in capital markets. Overall, in our first test, we assume that early disclosure is informative and document a change in liquidity. In this final test, we check whether firms that were effectively targeted for their drugs development post FDAAA (which confirms the usefulness of the disclosure) experience stronger improvement in liquidity. For this purpose, we estimate Model 3.

Model 3:

$$Spread\ 100_{i,q} = \beta_0 + \beta_1 \bullet Consequences + \beta_2 \bullet Consequences\ X\ Post + \sum \lambda n \bullet Controls_{i,q-1} + Firm\ Fixed\ Effects + Year\text{-}Quarter\ Fixed\ Effects + \varepsilon_{i,q.} \quad (3)$$

In Model 3, *Consequences* includes different measures of consequences, such as *FDA MAUDE*, *Ln Total FDA MAUDE*, *Adverse Event*, *Ln Total Adverse Event*, *Product Problem*, *Ln Total Product Problem*, *Recall*, and *Ln Total Recall*. The interaction term *Consequences X Post* is our variable of interest and we predict it to be negative if more consequences happen in firms with lower information asymmetry after the FDAAA. All the control variables are defined as for Model 1. Firm fixed effects and year-quarter fixed effects are included in the model. The variable *Post* is omitted as we have year-quarter fixed effects in the specification. Standard errors are clustered at the firm level.

6.2. Results

The tests on joint effects are executed only in time series within the subsample of pharmaceutical firms whose clinical trial results are subject to the FDAAA disclosure requirement. The subsample includes only the 163 pharmaceutical firms for the two-year period before and after the FDAAA. The subsample consists of 2,608 firm-quarter observations. The results in Table 10 show that the coefficients of all the interaction terms *Consequences X Post* are negative and significant at the 1% level across all the specifications, suggesting that pharmaceutical firms with non-missing consequence effects experience a larger reduction in information asymmetry after the FDAAA.

7. Conclusion

In this paper, we examine the impact of the Food and Drugs Administration Amendments Act (FDAAA) of 2007 on the disclosure of the clinical trial results of affected pharmaceutical firms. The FDAAA ultimately influenced the information asymmetry between

the pharmaceutical firm and its investors, as well as that between the firm and its consumers and the general public. We find that firms required to disclose information on their clinical trial results exhibit lower levels of information asymmetry in financial markets and are subject to more scrutiny by outside parties.

Pharmaceutical firms whose clinical trials are subject to the FDAAA experience a lower bid-ask spread after 2007. The scrutiny on clinical trials from the general public, academics, and practitioners also increased after the enactment of the FDAAA. Thus, those pharmaceutical firms also experience a higher incidence of FDA adverse event/product problem reports and drug and medical devices recalls after the enactment of the FDAAA. Finally, although adverse event/product problem reports and recalls are associated with high bid-ask spread firms before FDAAA adoption, the adverse event/product problem and recalls increased the most for firms with the highest increase in bid-ask spreads. We acknowledge that our second and third sets of tests on consequences of FDAAA outside capital markets suffer from the lack of a benchmark for our treatment group. Overall, our results suggest that a weakly enforced law still generates some positive benefits to investors, and it attracts attention and reaction from the general public.

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Appendix. Variable Definitions

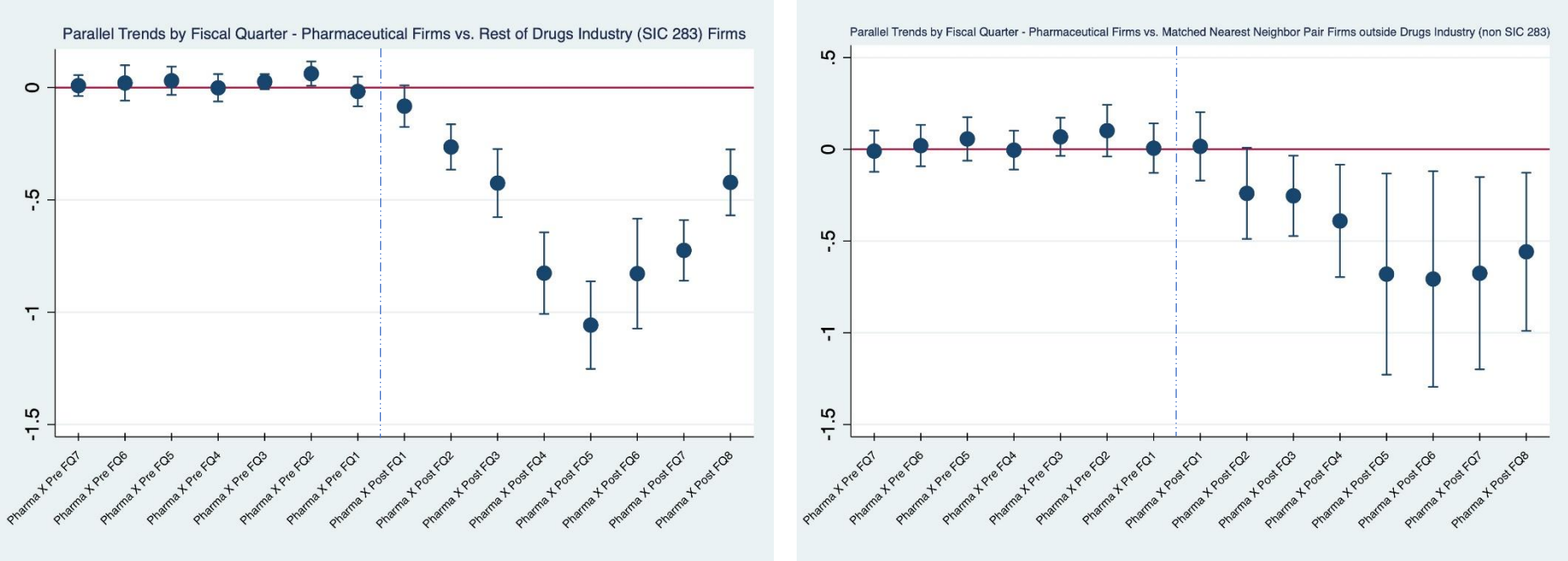
Variables	Data Source	Variable Definition
Dependent Variable and Major Variables of Interest		
Spread 100	CRSP	Average value of the daily bid-ask spread over the fiscal quarter, where the bid-ask spread is calculated as (ask-bid)/price using data on closing prices and quotes from CRSP, multiplied by 100 (to translate on basis point).
Post	Compustat	Binary variable, equal to 1, if data date is after September 27, 2007, the date when FDAAA 2007 took effect; zero otherwise.
Pharma	ClinicalTrials.gov	Binary variable, equal to 1, if the firm is in the list of firms whose clinical trials results should be disclosed on ClinicalTrials.gov website subject to FDAAA 2007 (Andersen et al., 2015); zero otherwise.
Pharma Submission	ClinicalTrials.gov	Binary variable, equal to 1, if the firm is in the list of firms whose clinical trials results should be disclosed on ClinicalTrials.gov website subject to FDAAA 2007 (Andersen et al., 2015) and did disclose clinical trial results; zero otherwise.
Pharma Early	ClinicalTrials.gov	Binary variable, equal to 1, if the firm is in the list of firms whose clinical trials results should be disclosed on ClinicalTrials.gov website subject to FDAAA 2007 (Andersen et al., 2015) and did disclose clinical trial results in a timely manner before trial due date at least once in the sample period; zero otherwise.
Firm-Level Control Variables		
Market Cap	Compustat	Market value of equity in millions USD at the end of the lagged fiscal quarter.
Ln Market Cap	Compustat	Natural logarithm form of 1 plus *Market Cap*.
Book-to-Market	Compustat	Book value of equity divided by market value of equity at the end of the lagged fiscal quarter.
Book Leverage	Compustat	Long term debt plus short term debt, scaled by total assets at the end of the lagged fiscal quarter.
ROA	Compustat	Return on assets, measured as income before extraordinary items scaled by total assets at the end of the lagged fiscal quarter.
Loss	Compustat	Binary variable, equal to 1, if income before extraordinary items at the lagged fiscal quarter is negative, and zero otherwise.
Quarterly Stock Return	CRSP	Cumulative daily stock return in CRSP over the lagged fiscal quarter.

Variables	Data Source	Variable Definition
Stock Return Volatility	CRSP	Standard deviation of daily stock return in CRSP over the lagged fiscal quarter.
Special Items	Compustat	Special items scaled by total assets at the end of the lagged fiscal quarter.
Consequences Measures for Pharmaceutical Firms		
FDA MAUDE	FDA MAUDE	Binary variable, equal to 1, if there is an adverse event or product problem report filed against the firm by reporters to FDA in MAUDE database during the fiscal quarter; zero otherwise.
Total FDA MAUDE (raw number in units)	FDA MAUDE	Total number of adverse event or product problem reports filed against the firm by reporters to FDA in MAUDE database during the fiscal quarter.
Ln Total FDA MAUDE (log form)	FDA MAUDE	Natural logarithm form of 1 plus *Total FDA MAUDE.*
Adverse Event	FDA MAUDE	Binary variable, equal to 1, if there is an adverse event report filed against the firm by reporters to the FDA in MAUDE database during the fiscal quarter; zero otherwise.
Total Adverse Event (raw number in units)	FDA MAUDE	Total number of adverse event reports filed against the firm by reporters to FDA in MAUDE database during the fiscal quarter.
Ln Total Adverse Event (log form)	FDA MAUDE	Natural logarithm form of 1 plus *Total Adverse Event.*
Product Problem	FDA MAUDE	Binary variable, equal to 1, if there is a product problem report filed against the firm by reporters to the FDA in MAUDE database during the fiscal quarter; zero otherwise.
Total Product Problem (raw number in units)	FDA MAUDE	Total number of product problem reports filed against the firm by reporters to the FDA in MAUDE database during the fiscal quarter.
Ln Total Product Problem (log form)	FDA MAUDE	Natural logarithm form of 1 plus *Total Product Problem.*
Recall	FDA	Binary variable, equal to 1, if the firm submits a drug or medical device recall during the fiscal quarter; zero otherwise.
Total Recall (raw number in units)	FDA	Total number of drug and medical device recalls filed during the fiscal quarter.
Ln Total Recall (log form)	FDA	Natural logarithm form of 1 plus *Total Recall*.
Total Recall / Total Completion Trials t-1	FDA and ClinicalTrials.gov	Ratio of the number of drug and medical device recalls during the fiscal year divided by the number of completed clinical trials in the lagged fiscal year.
Google "clinicaltrials.gov" US	Google Trends	Monthly Google trends web search records of keyword "clinicaltrials.gov" in the U.S. Value range is from 0 to 100.

Variables	Data Source	Variable Definition
Ln Google "clinicaltrials.gov" US	Google Trends	Natural logarithm form of 1 plus *Google "clinicaltrials.gov" US*.
Google "FDAAA" US	Google Trends	Monthly Google trends web search records of keyword "FDAAA" in the U.S. Value range is from 0 to 100.
Ln Google "FDAAA" US	Google Trends	Natural logarithm form of 1 plus *Google "FDAAA" US.*
Google "clinical trials" US	Google Trends	Monthly Google trends web search records of keyword "clinical trials" in the U.S. Value range is from 0 to 100.
Google "clinicaltrials.gov" / "clinical trials" US	Google Trends	Ratio of *Google "clinicaltrials.gov" US* scaled by *Google "clinical trials" US.*
Google Search Trend	Google Trends	Monthly Google trends web search records in the U.S. Value range is from 0 to 100.
Ln Google Search Trend	Google Trends	Natural logarithm form of 1 plus *Google Search Trend.*
Google clinicaltrials.gov	Google Trends	Binary variable, equal to 1, if the Google trends web search keyword is "clinicaltrials.gov", zero if the keyword is "clinical trials".
PubMed "clinicaltrials.gov"	PubMed.gov	Monthly trend of the number of medical research publications on PubMed.gov with keyword "clinicaltrials.gov". Value range is from 0 to 100.
Ln PubMed "clinicaltrials.gov"	PubMed.gov	Natural logarithm form of 1 plus *PubMed "clinicaltrials.gov".*
PubMed "clinical trials"	PubMed.gov	Monthly trend of the number of medical research publications on PubMed with keyword "clinical trials" Value range is from 0 to 100.
Ln PubMed "clinical trials"	PubMed.gov	Natural logarithm form of 1 plus *PubMed "clinical trials".*
PubMed "clinicaltrials.gov" / "clinical trials"	PubMed.gov	Ratio of *PubMed "clinicaltrials.gov"* scaled by *PubMed "clinical trials".*
PubMed.gov Search Trend	PubMed.gov	Monthly trend of the number of medical research publications on PubMed.gov. Value range is from 0 to 100.
Ln PubMed.gov Search Trend	PubMed.gov	Natural logarithm form of 1 plus *PubMed.gov Search Trend.*
PubMed clinicaltrials.gov	PubMed.gov	Binary variable, equal to 1, if the trend of the number of medical research publications on PubMed.gov keyword is "clinicaltrials.gov", zero if the keyword is "clinical trials".

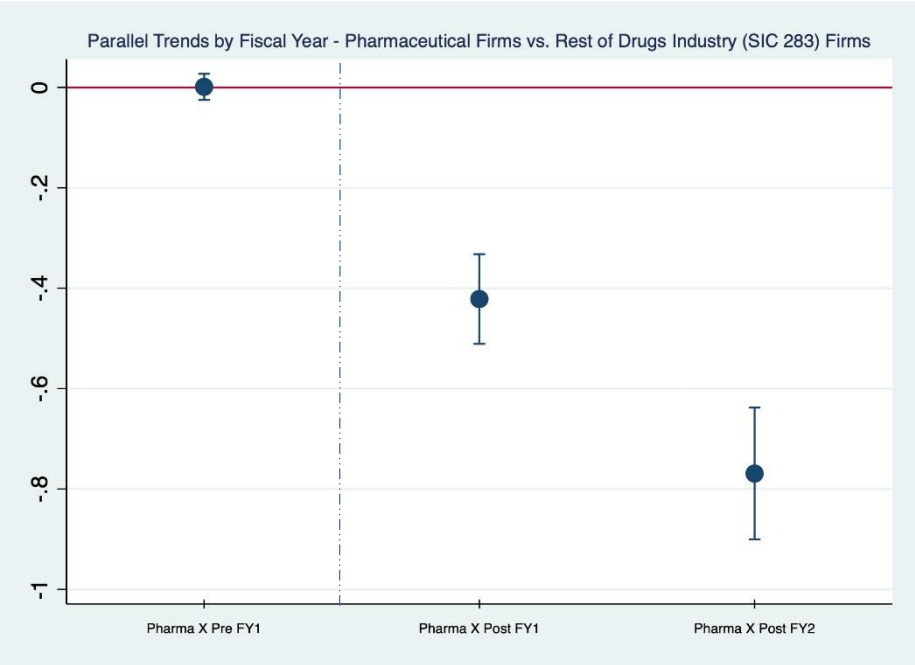
All continuous variables are winsorized at the 1st and 99th percentiles.

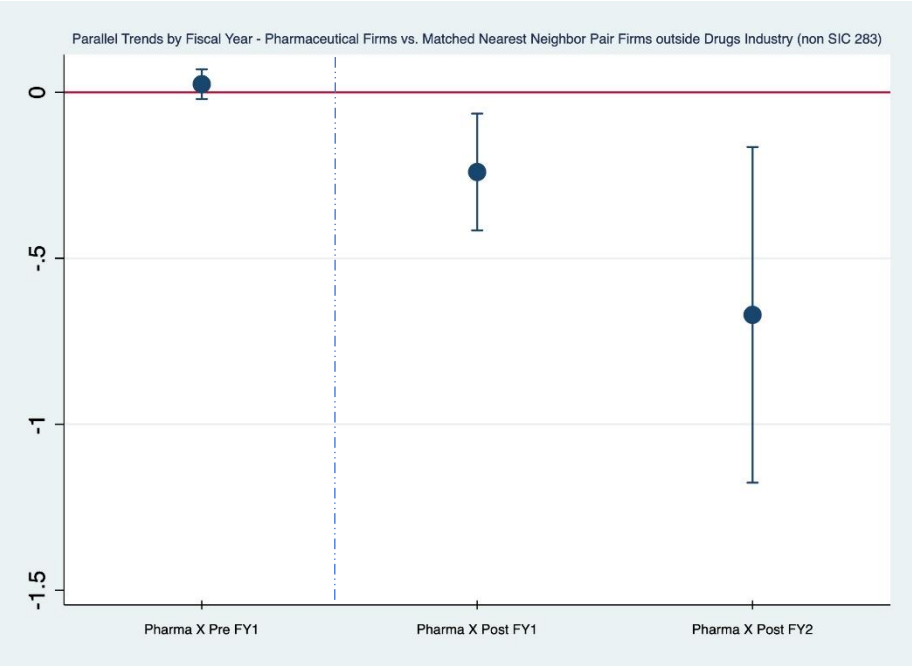
Figure 1. Parallel Trends Analysis for Pharmaceutical Firms vs. Control Groups
Panel A. Parallel Trends by Fiscal Quarter: Pharmaceutical Firms vs. Rest of the Drugs Industry Firms (Left) and Pharmaceutical Firms vs. Matched Nearest Neighbor Pair Firms outside the Drugs Industry (Right)



Panel A shows the results from column (1) of Table 5 Panel A with year-quarter and firm fixed effects in the left graph. It presents the parallel trend analysis results for pharmaceutical firms against the rest of the drugs industry by fiscal quarter before and after the FDAAA. The right graph shows the results from column (2) of Table 5 Panel A with year-quarter and firm fixed effects. It presents the parallel trend analysis results for pharmaceutical firms against the matched nearest neighbor pair firms outside the drugs industry by fiscal quarter before and after the FDAAA. The indicator for *Pharma X Pre FQ8* is omitted and serves as benchmark. The coefficient estimates for each quarter are plotted, along with their 95% confidence intervals.

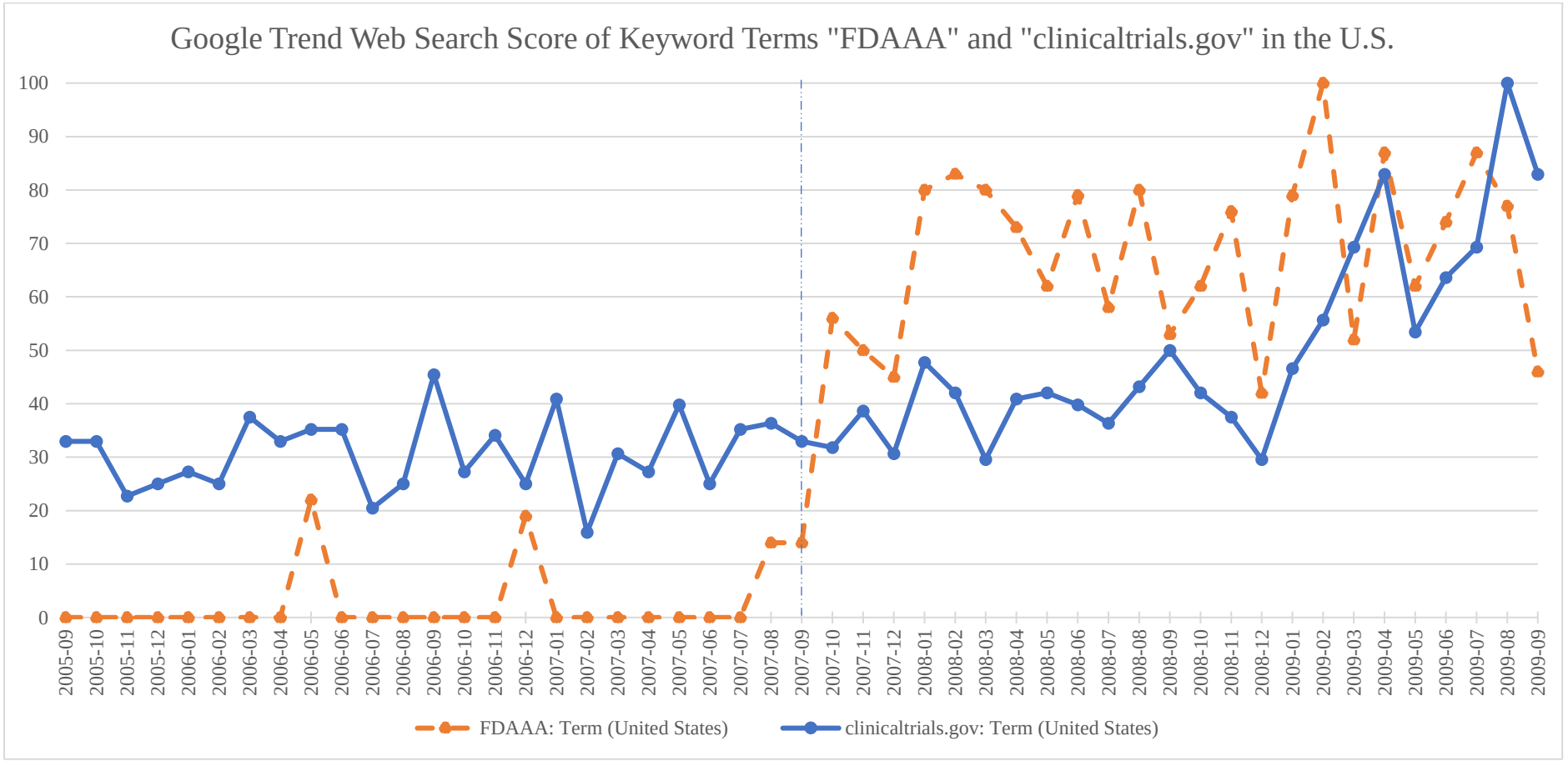
Panel B. Parallel Trends by Fiscal Year: Pharmaceutical Firms vs. Rest of the Drugs Industry Firms (Left) and Pharmaceutical Firms vs. Matched Nearest Neighbor Pair Firms outside the Drugs Industry (Right)





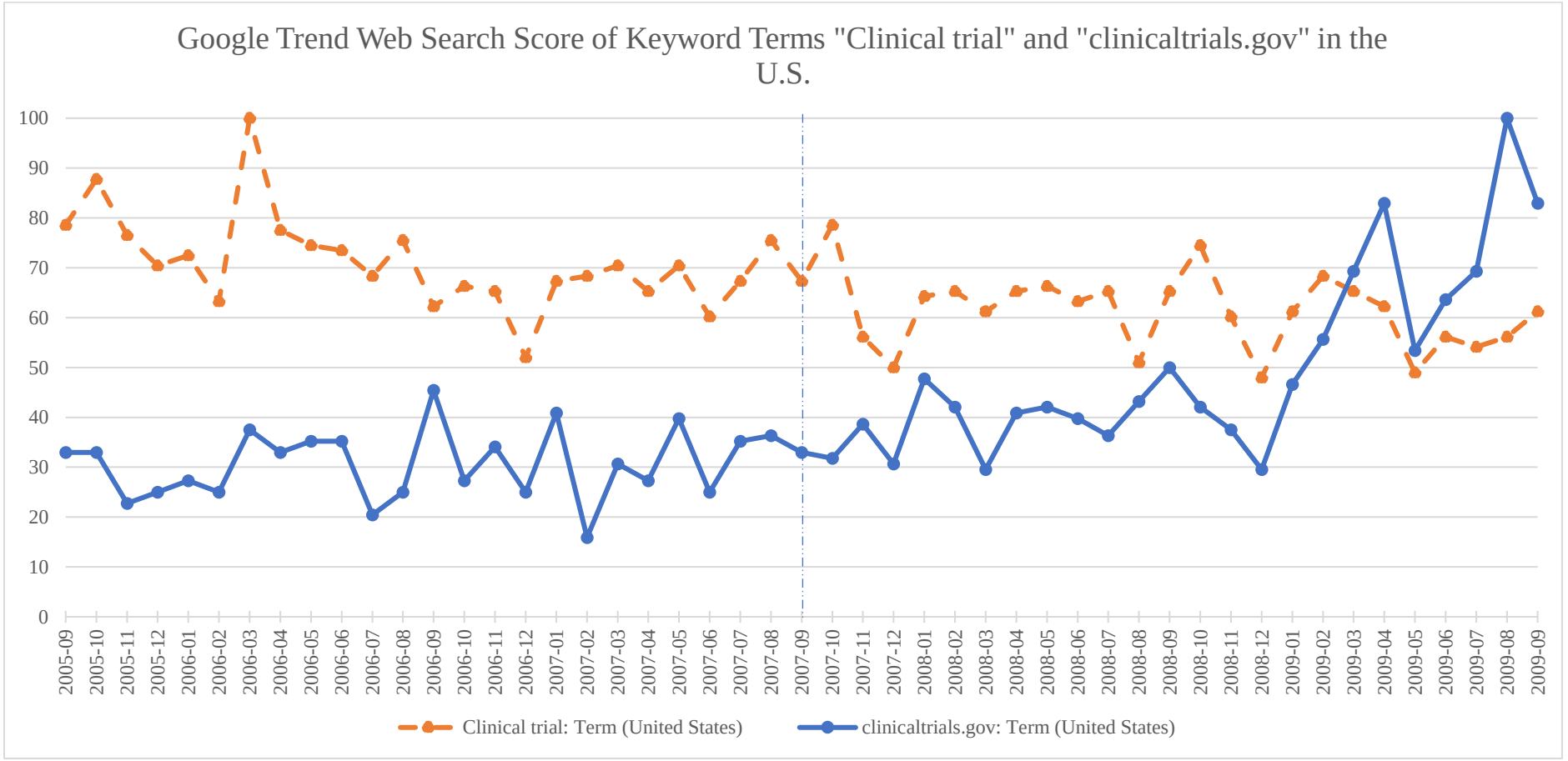
Panel B shows the results from column (1) of Table 5 Panel B with year-quarter and firm fixed effects in the left graph. It presents the parallel trend analysis for pharmaceutical firms against the rest of the drugs industry by fiscal year before and after the FDAAA. The right graph shows the results from column (2) of Table 5 Panel B with year-quarter and firm fixed effects. It presents the parallel trend analysis results for pharmaceutical firms against the matched nearest neighbor pair firms outside the drugs industry by fiscal year before and after the FDAAA. The indicator for *Pharma X Pre FY2* is omitted and serves as benchmark. The coefficient estimates for each year are plotted, along with their 95% confidence intervals.

Figure 2. Public and Research Community Attention on FDAAA
Panel A. Google Trend Web Search Score of Keyword Terms "FDAAA" and "clinicaltrials.gov" in the U.S.



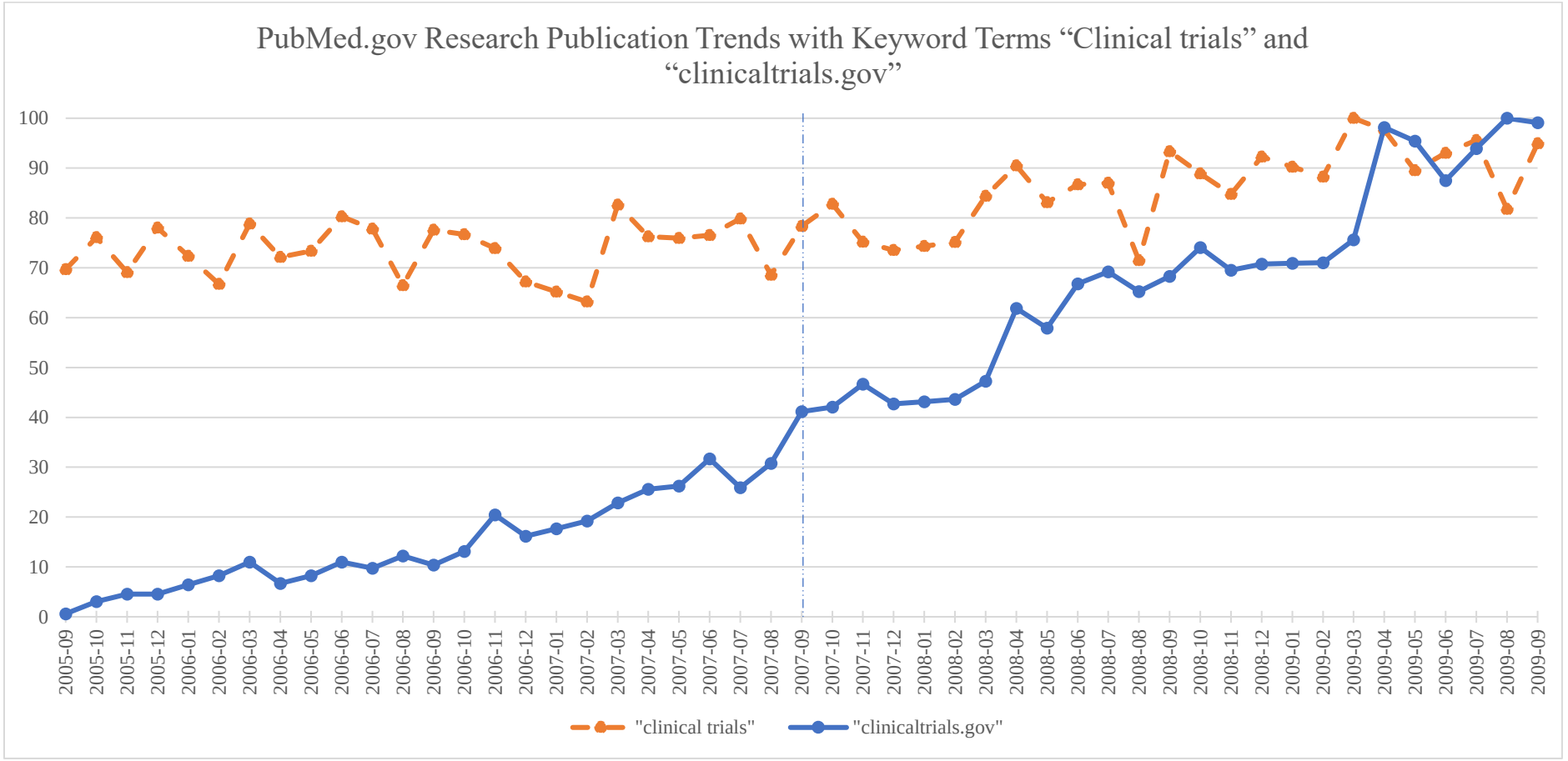
Panel A presents monthly trend analysis results for the September 2005 to September 2009 period for the Google Trends web search score in the U.S. of keyword term "FDAAA" (shown as dashed line) and of keyword term "clinicaltrials.gov" (shown as solid line) before and after the FDAAA in September 2007. The Google Trends web search score represents search interest relative to the highest point 100 on the chart over the sample period. A value of 100 is the peak popularity for the term; a value of 50 means that the term is half as popular; a value of 0 means there was not enough data for this term.

Panel B. Google Trend Web Search Score of Keyword Terms "Clinical trial" and "clinicaltrials.gov" in the U.S.



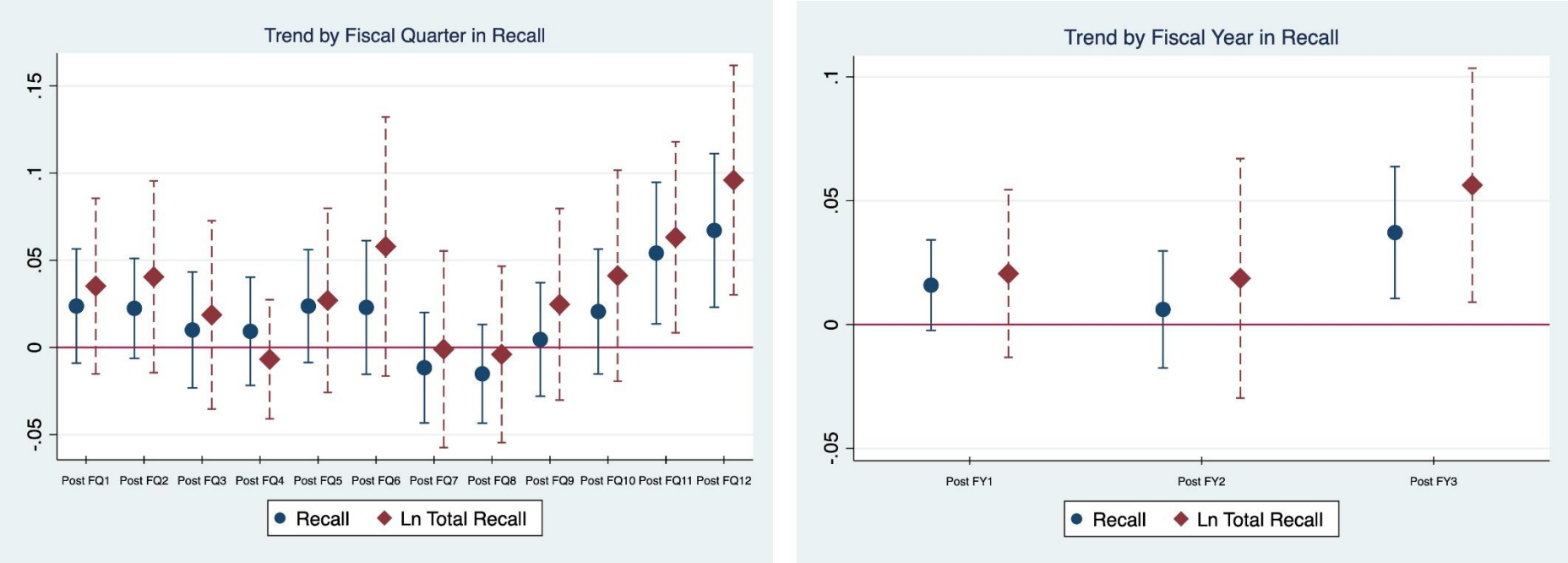
Panel B presents monthly trend analysis results for the September 2005 to September 2009 period for the Google Trends web search score in the U.S. of keyword term "Clinical trial" (shown as dashed line) and of keyword term "clinicaltrials.gov" (shown as solid line) before and after the FDAAA in September 2007. The Google Trends web search score represents search interest relative to the highest point 100 on the chart over the sample period. A value of 100 is the peak popularity for the term; a value of 50 means that the term is half as popular; a score of 0 means there was not enough data for this term.

Panel C. PubMed Research Publication Trends of Keyword Terms "Clinical trials" and "clinicaltrials.gov"



Panel C presents monthly trend analysis results for the September 2005 to September 2009 period for the research publications on PubMed.gov database of the keyword term "clinical trials" (shown as dashed line) and of keyword term "clinicaltrials.gov" (shown as solid line) before and after the FDAAA in September 2007. This trend is scaled relative to the highest point 100 on the chart over the sample period. A value of 100 is the peak for the number of publications related to the keyword.

Figure 3. Trends Analysis Results of Recalls for Pharmaceutical Firms by Quarter (Left) and by Year (Right) over the 24-Quarter Window



This figure shows the untabulated results from the trends analysis of recalls for pharmaceutical firms by fiscal quarter after the FDAAA in September 2007 in the left graph. The right graph shows the untabulated results from the trends analysis for pharmaceutical firms by fiscal year after the FDAAA. The indicators for the pre-period are omitted and serve as benchmark. The coefficient estimates for each quarter are plotted, along with their 95% confidence intervals.

Table 1 Descriptive Statistics

Variables	N	Mean	SD	p25	p50	p75
Panel A: Pharmaceutical Firms subject to FDAAA and Rest of the Drugs Industry (SIC 283) Firms						
Dependent Variable and Major Variables of Interest						
Spread 100	3,616	0.801	1.449	0.111	0.263	0.780
Post	3,616	0.500	0.500	0.000	0.500	1.000
Pharma	3,616	0.721	0.448	0.000	1.000	1.000
Pharma Submission	3,616	0.500	0.500	0.000	0.500	1.000
Pharma Early	3,616	0.319	0.466	0.000	0.000	1.000
Firm-Level Control Variables						
Market Cap (raw number in millions USD)	3,616	5,444.000	14,619.000	123.600	328.700	1,550.000
Ln Market Cap (log form)	3,616	6.233	2.089	4.825	5.798	7.347
Book-to-Market	3,616	0.433	0.256	0.247	0.375	0.551
Book Leverage	3,616	0.170	0.226	0.000	0.068	0.267
ROA	3,616	-0.055	0.096	-0.111	-0.027	0.020
Loss	3,616	0.582	0.493	0.000	1.000	1.000
Quarterly Stock Return	3,616	0.016	0.283	-0.150	-0.002	0.142
Stock Return Volatility	3,616	0.037	0.023	0.022	0.032	0.045
Special Items	3,616	-0.004	0.018	-0.001	0.000	0.000
Panel B: Pharmaceutical Firms Subject to FDAAA and Matched Nearest Neighbor Pair Firms Outside the Drugs Industry (non SIC 283)						
Dependent Variable and Major Variables of Interest						
Spread 100	5,184	0.865	1.628	0.111	0.253	0.857
Post	5,184	0.500	0.500	0.000	0.500	1.000
Pharma	5,184	0.500	0.500	0.000	0.500	1.000
Pharma Submission	5,184	0.346	0.476	0.000	0.000	1.000
Pharma Early	5,184	0.222	0.416	0.000	0.000	0.000
Firm-Level Control Variables						
Market Cap (raw number in millions USD)	5,184	5,921.000	15,551.000	99.670	328.700	1,630.000
Ln Market Cap (log form)	5,184	6.183	2.220	4.612	5.798	7.397
Book-to-Market	5,184	0.480	0.284	0.270	0.419	0.631
Book Leverage	5,184	0.151	0.217	0.000	0.043	0.234
ROA	5,184	-0.043	0.090	-0.090	-0.006	0.019
Loss	5,184	0.531	0.499	0.000	1.000	1.000
Quarterly Stock Return	5,184	0.012	0.284	-0.159	-0.004	0.141
Stock Return Volatility	5,184	0.037	0.023	0.023	0.032	0.045
Special Items	5,184	-0.005	0.018	-0.001	0.000	0.000
Panel C: Subsample of Pharmaceutical Firms Subject to FDAAA, where *Pharma* = 1						
FDA MAUDE	2,608	0.133	0.340	0.000	0.000	0.000
Total FDA MAUDE (raw number in units)	2,608	56.200	361.700	0.000	0.000	0.000
Ln Total FDA MAUDE (log form)	2,608	0.513	1.551	0.000	0.000	0.000
Adverse Event	2,608	0.121	0.326	0.000	0.000	0.000
Total Adverse Event (raw number in units)	2,608	21.170	145.500	0.000	0.000	0.000
Ln Total Adverse Event (log form)	2,608	0.397	1.254	0.000	0.000	0.000
Product Problem	2,608	0.108	0.310	0.000	0.000	0.000
Total Product Problem (raw number in units)	2,608	37.330	251.100	0.000	0.000	0.000
Ln Total Product Problem (log form)	2,608	0.423	1.401	0.000	0.000	0.000
Recall	2,608	0.055	0.228	0.000	0.000	0.000
Total Recall (raw number in units)	2,608	0.340	2.981	0.000	0.000	0.000
Ln Total Recall (log form)	2,608	0.072	0.326	0.000	0.000	0.000

This table presents descriptive statistics for the variables used in the analysis for three different samples. In Panel A, the first sample consists of 163 pharmaceutical firms subject to the FDAAA and 63 firms in the drugs industry (SIC code 283), which include in total 226 U.S. firms and 3,616 firm-quarter observations over the 2005 to 2009 period. In Panel B, the sample consists of 162 pharmaceutical firms subject to the FDAAA and 162 matched nearest neighbor pair firms outside the drugs industry (SIC code different from 283), which includes 324 U.S. firms and 5,184 firm-quarter observations over the 2005 to 2009 period. In Panel C, the sample is the subsample of pharmaceutical firms whose clinical trials are subject to the FDAAA and consists of 2,608 firm-quarter observations from 163 pharmaceutical firms over 2005 to 2009 period. We collect clinical trial data from the Aggregate Analysis of ClincalTrials.gov (AACT) database obtained through Clinical Trials Transformation Initiative (CTTI) website, whose data source is ClinicalTrials.gov website as of March 27, 2015. We match clinical trials data by company name with Compustat and CRSP to get financial statement data. See the Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles.

Table 2. Univariate Analysis Results of Treatment Group and Control Group
Panel A: Pharmaceutical Firms subject to FDAAA vs. the Rest of the Drugs Industry (SIC 283) Firms

	(1)	(2)	(1) - (2)	
	Pharmaceutical Firms subject to FDAAA	Rest of the Drugs Industry (SIC 283) Firms		
	163 firm observations	63 firm observations		
Variables	72.12%	27.88%		
Spread 100	0.335	0.725	-0.390	***
Market Cap	7761.608	678.395	7083.213	***
Ln Market Cap	6.777	5.551	1.226	***
Book-to-Market	0.350	0.418	-0.068	**
Book Leverage	0.173	0.132	0.041	
ROA	-0.062	-0.047	-0.015	
Loss	0.626	0.524	0.102	
Quarterly Stock Return	0.031	0.024	0.007	
Stock Return Volatility	0.028	0.030	-0.002	
Special Items	-0.003	-0.005	0.002	

This panel presents univariate comparison in the averages of dependent variable and all the control variables between pharmaceutical firms subject to FDAAA in the treatment group and the rest of the drugs industry (SIC code 283) firms in the control group for the last fiscal quarter before the regulatory change. Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Panel B: Pharmaceutical Firms subject to FDAAA vs. Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)

	(1)	(2)	(1) - (2)	
	Pharmaceutical Firms subject to FDAAA	Matched Nearest Neighbor Pair Firms outside the Drugs Industry (non SIC 283)		
	162 firm observations	162 firm observations		
	50.00%	50.00%		
Spread 100	0.332	0.598	-0.266	***
Market Cap	7809.119	4687.408	3121.711	*
Ln Market Cap	6.793	5.999	0.794	***
Book-to-Market	0.351	0.454	-0.103	***
Book Leverage	0.174	0.119	0.054	**
ROA	-0.061	-0.024	-0.036	***
Loss	0.623	0.500	0.123	**
Quarterly Stock Return	0.031	0.030	0.002	
Stock Return Volatility	0.028	0.029	-0.001	
Special Items	-0.003	-0.004	0.001	

This panel presents univariate comparison in the averages of dependent variable and all the control variables between pharmaceutical firms subject to FDAAA in the treatment group and the matched nearest neighbor pair firms outside the drugs industry (SIC code different from 283) in the control group for the last fiscal quarter before the regulatory change. Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 3. Baseline Regression Results

Variables	(1) *Spread 100*	(2) *Spread 100*	(3) *Spread 100*	(4) *Spread 100*
Pharma X Post	**-0.6984*** **	**-0.5971*** **	**-0.5338*** **	**-0.4671*** **
	(-9.78)	(-10.97)	(-3.17)	(-2.82)
Ln Market Cap		-0.8280***		-0.6211***
		(-36.54)		(-6.07)
Book-to-Market		0.3575*		0.5476*
		(1.96)		(1.91)
Book Leverage		-0.1889***		0.0506
		(-3.02)		(0.26)
ROA		0.4214**		-0.3555
		(2.88)		(-1.18)
Loss		0.2316***		-0.0706
		(3.15)		(-1.07)
Quarterly Stock Return		-0.0555*		-0.0999*
		(-1.78)		(-1.74)
Stock Return Volatility		5.1532***		11.4859**
		(12.43)		(2.19)
Special Items		2.2243***		2.2163**
		(8.62)		(2.65)
Constant	1.0525***	5.7621***	0.9989***	4.1569***
	(40.89)	(21.11)	(23.70)	(4.61)
Observations	3,616	3,616	5,184	5,184
Adjusted R-squared	0.5917	0.6977	0.5998	0.6652
Sample period	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each
Control group	Rest of Drugs Industry (SIC 283) Firms	Rest of Drugs Industry (SIC 283) Firms	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)
Year-Quarter FE	YES	YES	YES	YES
Firm FE	YES	YES	YES	YES
Model	OLS	OLS	OLS	OLS
Standard error	Industry-level	Industry-level	Industry-level	Industry-level

This table presents regression results pertaining to the difference-in-difference analysis of bid-ask spread change before and after the FDAAA in the treatment group versus the control group. The treatment group includes pharmaceutical firms whose clinical trial results are required to be disclosed following the FDAAA. Control groups are the rest of the drugs industry (SIC code 283) in columns (1) and (2) and the matched nearest neighbor pair firms outside the drugs industry (SIC code different from 283) in columns (3) and (4). Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. Robust *t*-statistics are in parentheses. Standard errors are clustered at the SIC 3-digit industry level. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 4. Pharmaceutical Firms Alternative Treatment Group Test

Variables	(1) *Spread 100*	(2) *Spread 100*	(3) *Spread 100*	(4) *Spread 100*
Pharma Submission X Post	**-0.4350*** **		**-0.4420*** **	
	(-14.08)		(-3.23)	
Pharma Early X Post		**-0.3072** **		**-0.3745*** **
		(-2.79)		(-3.67)
Constant	5.5354***	5.4700***	4.0216***	3.9624***
	(15.05)	(13.01)	(4.71)	(4.73)
Observations	3,616	3,616	5,184	5,184
Adjusted R-squared	0.6947	0.6913	0.6641	0.6621
Sample period	Balanced 16 quarters / 8 quarters in the pre- and post-period each	Balanced 16 quarters / 8 quarters in the pre- and post-period each	Balanced 16 quarters / 8 quarters in the pre- and post-period each	Balanced 16 quarters / 8 quarters in the pre- and post-period each
Control group	Rest of Drugs Industry (SIC 283) Firms	Rest of Drugs Industry (SIC 283) Firms	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)
Control variables	YES	YES	YES	YES
Year-Quarter FE	YES	YES	YES	YES
Firm FE	YES	YES	YES	YES
Model	OLS	OLS	OLS	OLS
Standard error	Industry-level	Industry-level	Industry-level	Industry-level

This table presents regression results pertaining to the difference-in-difference analysis of bid-ask spread change before and after FDAAA regulatory change in treatment group as opposed to control group. Treatment group includes pharmaceutical firms whose clinical trial results are required to be disclosed following FDAAA requirement and who indeed disclosed their results in columns (1) and (3). Treatment group includes pharmaceutical firms whose clinical trial results are required to be disclosed following FDAAA requirement and who indeed disclosed their results on time within the required disclosure period in columns (2) and (4). Control groups are the rest of the drugs industry firms (SIC code 283) in columns (1) and (2) and the matched nearest neighbor pair firms outside the drugs industry (SIC code different from 283) in columns (3) and (4). Firm-level control variables are the same as those in the baseline model in Table 3. Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. Robust *t*-statistics are shown in parentheses. Standard errors are clustered at the SIC 3-digit industry level. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 5. Parallel Trend Analysis for Pharmaceutical Firms by Quarter and Year
Panel A: Parallel Trend Analysis for Pharmaceutical Firms by Quarter

Variables	(1) ***Spread 100***	(2) ***Spread 100***
Pharma X Pre FQ7	0.0088	-0.0097
	(0.40)	(-0.17)
Pharma X Pre FQ6	0.0205	0.0201
	(0.55)	(0.36)
Pharma X Pre FQ5	0.0303	0.0567
	(1.03)	(0.96)
Pharma X Pre FQ4	-0.0012	-0.0045
	(-0.04)	(-0.08)
Pharma X Pre FQ3	0.0262	0.0679
	(1.68)	(1.31)
Pharma X Pre FQ2	0.0621**	0.1017
	(2.45)	(1.45)
Pharma X Pre FQ1	-0.0173	0.0062
	(-0.56)	(0.09)
Pharma X Post FQ1	**-0.0829***	**0.0160**
	(-1.91)	(0.17)
Pharma X Post FQ2	**-0.2645*****	**-0.2401***
	(-5.59)	(-1.94)
Pharma X Post FQ3	**-0.4252*****	**-0.2535****
	(-5.97)	(-2.32)
Pharma X Post FQ4	**-0.8261*****	**-0.3904****
	(-9.69)	(-2.55)
Pharma X Post FQ5	**-1.0575*****	**-0.6804****
	(-11.57)	(-2.49)
Pharma X Post FQ6	**-0.8282*****	**-0.7070****
	(-7.22)	(-2.41)
Pharma X Post FQ7	**-0.7249*****	**-0.6753****
	(-11.45)	(-2.58)
Pharma X Post FQ8	**-0.4222*****	**-0.5584****
	(-6.14)	(-2.60)
Constant	5.7998***	4.2044***
	(23.09)	(4.56)
Observations	3,616	5,184
Adjusted R-squared	0.7016	0.6672
Sample period	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each
Control group	Rest of Drugs Industry (SIC 283) Firms	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)
Control variables	YES	YES
Year-Quarter FE	YES	YES
Firm FE	YES	YES
Model	OLS	OLS
Standard error	Industry-level	Industry-level

This table panel presents parallel trend regression results pertaining to the difference-in-difference analysis of bid-ask spread change by quarter before and after FDAAA regulatory change in treatment group as opposed to control group. Treatment group includes pharmaceutical firms whose clinical trial results are required to be disclosed following FDAAA requirement. Control groups are the rest of the drugs industry firms (SIC code 283) in column (1) and the matched nearest neighbor pair firms outside the drugs industry (SIC code different from 283) in column (2). Firm-level control variables are the same as those in the baseline model in Table 3. Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. Robust *t*-statistics are shown in parentheses. Standard errors are clustered at the SIC 3-digit industry level. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Panel B: Parallel Trend Analysis for Pharmaceutical Firms by Year

Variables	(1) ***Spread 100***	(2) ***Spread 100***
Pharma X Pre FY1	0.0012	0.0246
	(0.10)	(1.10)
Pharma X Post FY1	**-0.4215*** **	**-0.2401*** **
	(-10.06)	(-2.73)
Pharma X Post FY2	**-0.7692*** **	**-0.6704** **
	(-12.48)	(-2.66)
Constant	5.7911***	4.1880***
	(22.80)	(4.55)
Observations	3,616	5,184
Adjusted R-squared	0.6992	0.6673
Sample period	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each
Control group	Rest of Drugs Industry (SIC 283) Firms	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)
Control variables	YES	YES
Year-Quarter FE	YES	YES
Firm FE	YES	YES
Model	OLS	OLS
Standard error	Industry-level	Industry-level

This table panel presents parallel trend regression results pertaining to the difference-in-difference analysis of bid-ask spread change by year before and after FDAAA regulatory change in treatment group as opposed to control group. Treatment group includes pharmaceutical firms whose clinical trial results are required to be disclosed following FDAAA requirement. Control groups are the rest of the drugs industry firms (SIC code 283) in column (1) and the matched nearest neighbor pair firms outside the drugs industry (SIC code different from 283) in column (2). Firm-level control variables are the same as those in the baseline model in Table 3. Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. Robust *t*-statistics are shown in parentheses. Standard errors are clustered at the SIC 3-digit industry level. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 6. Robustness Tests
Panel A: Robustness Test – Baseline Model in Different Sample Period Windows

Variables	(1) *Spread 100*	(2) *Spread 100*	(3) *Spread 100*	(4) *Spread 100*	(5) *Spread 100*	(6) *Spread 100*	(7) *Spread 100*	(8) *Spread 100*
Pharma X Post	**-0.3791*** **	**-0.3425*** **	**-0.4142*** **	**-0.2453*** **	**-0.3121*** **	**-0.1950** **	**-0.2645*** **	**-0.1599** **
	(-9.80)	(-3.09)	(-10.50)	(-2.75)	(-8.06)	(-2.52)	(-7.57)	(-2.38)
Constant	4.9373***	4.1133***	4.6294***	4.5478***	3.6755***	4.4742***	2.8107***	4.6938***
	(48.72)	(6.85)	(21.98)	(5.77)	(15.44)	(7.47)	(8.22)	(7.31)
Observations	4,632	6,816	1,808	2,592	1,356	1,944	904	1,296
Adjusted R-squared	0.7049	0.6899	0.7670	0.7270	0.8067	0.7506	0.8023	0.7434
Sample period	Balanced 24 quarters / 12 quarters in the pre- and post-period each	Balanced 24 quarters / 12 quarters in the pre- and post-period each	Balanced 8 quarters / 4 quarters in the pre- and post-period each	Balanced 8 quarters / 4 quarters in the pre- and post-period each	Balanced 6 quarters / 3 quarters in the pre- and post-period each	Balanced 6 quarters / 3 quarters in the pre- and post-period each	Balanced 4 quarters / 2 quarters in the pre- and post-period each	Balanced 4 quarters / 2 quarters in the pre- and post-period each
Control group	Rest of Drugs Industry (SIC 283) Firms	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)	Rest of Drugs Industry (SIC 283) Firms	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)	Rest of Drugs Industry (SIC 283) Firms	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)	Rest of Drugs Industry (SIC 283) Firms	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)
Control variables	YES	YES	YES	YES	YES	YES	YES	YES
Year-Quarter FE	YES	YES	YES	YES	YES	YES	YES	YES
Firm FE	YES	YES	YES	YES	YES	YES	YES	YES
Year-Quarter X State FE	NO	NO	NO	NO	NO	NO	NO	NO
Model	OLS	OLS	OLS	OLS	OLS	OLS	OLS	OLS
Standard error	Industry-level	Industry-level	Industry-level	Industry-level	Industry-level	Industry-level	Industry-level	Industry-level

This table presents robustness tests on regression results pertaining to the difference-in-difference analysis of bid-ask spread change before and after FDAAA regulatory change in treatment group as opposed to control group in different sample period windows. Treatment group includes pharmaceutical firms whose clinical trial results are required to be disclosed following FDAAA requirement. Control groups are the rest of the drugs industry (SIC code 283) in columns (1), (3), (5) and (7), and the matched nearest neighbor pair firms outside the drugs industry (SIC code different from 283) in columns (2), (4), (6) and (8). Sample period in columns (1) and (2) is extended to 24 quarters (6 years) with 12 quarters (3 years) in pre and post period each of regulatory change, while sample period in columns (3) and (4) is shortened to 8 quarters (2 years) with 4 quarters (1 year) in pre and post period each of regulatory change. Sample period in columns (5) through (8) is shortened to less than 8 quarters (2 years), with 6 quarters in columns (5) and (6), and 4 quarters in columns (7) and (8). Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. Robust *t*-statistics are shown in parentheses. Standard errors are clustered at the SIC 3-digit industry level. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Panel B: Robustness Test – Baseline Model with Year-Quarter X State Fixed Effects and Compustat Firms as Control Group

Variables	(1) *Spread 100*	(2) *Spread 100*	(3) *Spread 100*
Pharma X Post	**-0.4895*** **	**-0.3677*** **	**-0.2646*** **
	(-6.79)	(-2.69)	(-2.65)
Constant	5.6526***	4.6101***	4.9283***
	(35.98)	(5.32)	(5.17)
Observations	3,536	5,016	50,816
Adjusted R-squared	0.6962	0.6793	0.6755
Sample period	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each
Control group	Rest of Drugs Industry (SIC 283) Firms	Matched Nearest Neighbor Pair Firms outside Drugs Industry (non SIC 283)	Rest of Compustat Firms
Control variables	YES	YES	YES
Year-Quarter FE	NO	NO	YES
Firm FE	YES	YES	YES
Year-Quarter X State FE	YES	YES	NO
Model	OLS	OLS	OLS
Standard error	Industry-level	Industry-level	Industry-level

This table presents robustness tests on regression results pertaining to the difference-in-difference analysis of bid-ask spread change before and after FDAAA regulatory change in treatment group as opposed to control group. Treatment group includes pharmaceutical firms whose clinical trial results are required to be disclosed following FDAAA requirement. Control groups are the rest of the drugs industry (SIC code 283) in column (1), the matched nearest neighbor pair firms outside the drugs industry (SIC code different from 283) in column (2), and the rest of Compustat firms in column 3. Year-Quarter fixed effects are replaced by Year-Quarter X State fixed effects in columns (1) and (2). Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. Robust *t*-statistics are shown in parentheses. Standard errors are clustered at the SIC 3-digit industry level. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 7. Google Trends Web Search and PubMed Research Trends in the U.S.

Panel A: Google Trends Web Search

Variables	(1) *Ln Google "clinicaltrials.gov" US*	(2) *Ln Google "FDAAA" US*	(3) *Google "clinicaltrials.gov" / "clinical trials" US*	(4) *Ln Google Search Trend*
Post	**0.4513*** **	**3.8463*** **	**0.4011*** **	**-0.1498** **
	(5.41)	(18.38)	(5.54)	(-2.34)
Google clinicaltrials.gov				-0.8428***
				(-13.16)
Google clinicaltrials.gov X Post				**0.6056*** **
				(6.69)
Constant	3.4287***	0.3683**	0.4343***	4.2698***
	(58.10)	(2.49)	(8.49)	(94.30)
Observations	48	48	48	96
Adjusted R-squared	0.3754	0.8775	0.3873	0.6728
Sample period	Balanced 48 months / 24 months in the pre- and post- period each	Balanced 48 months / 24 months in the pre- and post- period each	Balanced 48 months / 24 months in the pre- and post- period each	Balanced 48 months / 24 months in the pre- and post- period each
Scope	U.S.	U.S.	U.S.	U.S.
Model	OLS	OLS	OLS	OLS
Subsample	Google Trend Web Search	Google Trend Web Search	Google Trend Web Search	Google Trend Web Search

Panel B: PubMed Research Trends

Variables	(1) *Ln PubMed "clinicaltrials.gov"*	(2) *Ln PubMed "clinical trials"*	(3) *PubMed "clinicaltrials.gov" / "clinical trials"*	(4) *Ln PubMed.gov Research Trend*
Post	**1.6878*** **	**0.1582*** **	**0.5971*** **	**0.1582**
	(10.56)	(6.51)	(13.26)	(1.43)
PubMed clinicaltrials.gov				-1.7713***
				(-16.03)
PubMed clinicaltrials.gov X Post				**1.5197*** **
				(9.73)
Constant	2.5265***	4.3085***	0.1966***	4.3087***
	(22.35)	(250.56)	(6.17)	(55.16)
Observations	48	48	48	96
Adjusted R-squared	0.7015	0.4679	0.7882	0.8070
Sample period	Balanced 48 months / 24 months in the pre- and post- period each	Balanced 48 months / 24 months in the pre- and post- period each	Balanced 48 months / 24 months in the pre- and post- period each	Balanced 48 months / 24 months in the pre- and post- period each
Model	OLS	OLS	OLS	OLS
Subsample	PubMed.gov	PubMed.gov	PubMed.gov	PubMed.gov

This table presents regression results pertaining to the monthly trend analysis over the 48-month period from September 2005 to September 2009 about Google Trends Web Search in Panel A and PubMed Research Trends in Panel B before and after FDAAA regulatory change. Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. Robust *t*-statistics are shown in parentheses. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 8. Time Trend of Clinical Trials, FDA MDR Complaint Reports in the MAUDE database and Recalls by Fiscal Year

Fiscal year	Clinical trial completion	Clinical trial results disclosure	FDA MAUDE Recorded Events	Adverse Events	Product Problems	Total recall	Drug recall	Medical device recall	Total recall / Total clinical trial completion
Pre FY3	585	0	17,558	5,140	13,244	113	0	113	19.32%
Pre FY2	710	0	27,955	7,415	21,658	105	1	104	14.79%
Pre FY1	938	0	22,363	9,760	14,684	133	3	130	14.18%
Post FY1	1,230	12	36,963	14,993	25,205	240	1	239	19.51%
Post FY2	1,466	409	59,237	23,009	35,796	410	6	404	27.97%
Post FY3	1,358	552	74,453	29,450	50,308	482	21	461	35.49%

This table presents time trend and summary statistics of clinical trials, FDA MAUDE recorded complaint reports and total recalls by fiscal year from 3 years before to 3 years after the implementation of regulation in September 2007.

Table 9. Effect of FDAAA Regulation on FDA MAUDE Complaint Reports and Total Recalls

Panel A: Sixteen-Quarter Window Results

Variables	(1) *FDA MAUDE*	(2) *Ln Total FDA MAUDE*	(3) *Adverse Event*	(4) *Ln Total Adverse Event*	(5) *Product Problem*	(6) *Ln Total Product Problem*	(7) *Recall*	(8) *Ln Total Recall*
Post	**0.0213***	**0.1091*****	**0.0182***	**0.0652*****	**0.0062**	**0.1139****	**0.0091**	**0.0151**
	(1.68)	(3.19)	(1.70)	(2.74)	(0.66)	(2.57)	(1.04)	(1.00)
Constant	-0.0544	0.2564	-0.0135	0.0637	-0.0112	0.2753	-0.0498	-0.1471
	(-0.57)	(1.12)	(-0.13)	(0.37)	(-0.15)	(1.25)	(-0.77)	(-1.26)
Observations	2,608	2,608	2,608	2,608	2,608	2,608	2,608	2,608
Adjusted R-squared	0.7586	0.9341	0.7648	0.9406	0.8202	0.9138	0.5117	0.5546
Sample period	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each
Control variables	YES	YES	YES	YES	YES	YES	YES	YES
Year-Quarter FE	NO	NO	NO	NO	NO	NO	NO	NO
Firm FE	YES	YES	YES	YES	YES	YES	YES	YES
Model	OLS	OLS	OLS	OLS	OLS	OLS	OLS	OLS
Standard error	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level
Subsample	Pharmaceutical Firms subject to FDAAA							

This table presents subsample regression results pertaining to the trend analysis of consequences before and after FDAAA regulatory change within the pharmaceutical firms in the treatment group over the 16-quarter (4-year) period. This subsample includes pharmaceutical firms whose clinical trial results are required to be disclosed following FDAAA requirement. *FDA MAUDE* is a binary variable equal to 1 if the firm was reported by a third party to FDA due to adverse event or product problem, 0 otherwise. *Ln Total FDA MAUDE* represents the log form of the number of FDA MAUDE complaint reports. *Adverse Event* is a binary variable equal to 1 if the firm was reported by a third party to FDA due to adverse event, 0 otherwise. *Ln Total Adverse Event* represents the log form of the number of FDA complaint reports due to adverse event. *Product Problem* is a binary variable equal to 1 if the firm was reported by a third party to FDA due to product problem, 0 otherwise. *Ln Product Problem* represents the log form of the number of FDA MAUDE complaint reports due to product problem. *Recall* is a binary variable equal to 1 if the firm has made a recall, 0 otherwise. *Ln Total Recall* represents the log form of the number of total recalls including both drug and medical device recalls. Firm-level control variables are the same as those in the baseline model in Table 3. Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. Robust *t*-statistics are shown in parentheses. Standard errors are clustered at the firm level. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Panel B: Twenty-Four-Quarter Window Results

Variables	(1) *FDA MAUDE*	(2) *Ln Total FDA MAUDE*	(3) *Adverse Event*	(4) *Ln Total Adverse Event*	(5) *Product Problem*	(6) *Ln Total Product Problem*	(7) *Recall*	(8) *Ln Total Recall*
Post	**0.0282****	**0.1671*****	**0.0245****	**0.1106*****	**0.0128**	**0.1601*****	**0.0217****	**0.0335***
	(2.24)	(3.32)	(2.17)	(3.46)	(1.45)	(2.64)	(2.58)	(1.93)
Constant	-0.0119	0.3388	0.0056	0.0265	0.0300	0.3683	-0.1215*	-0.2243*
	(-0.15)	(1.07)	(0.07)	(0.17)	(0.44)	(1.08)	(-1.69)	(-1.80)
Observations	3,408	3,408	3,408	3,408	3,408	3,408	3,408	3,408
Adjusted R-squared	0.7858	0.9153	0.7891	0.9237	0.8183	0.8948	0.4749	0.5302
Sample period	Balanced 24 quarters / 12 quarters in the pre- and post-period each	Balanced 24 quarters / 12 quarters in the pre- and post-period each	Balanced 24 quarters / 12 quarters in the pre- and post-period each	Balanced 24 quarters / 12 quarters in the pre- and post-period each	Balanced 24 quarters / 12 quarters in the pre- and post-period each	Balanced 24 quarters / 12 quarters in the pre- and post-period each	Balanced 24 quarters / 12 quarters in the pre- and post-period each	Balanced 24 quarters / 12 quarters in the pre- and post-period each
Control variables	YES	YES	YES	YES	YES	YES	YES	YES
Year-Quarter FE	NO	NO	NO	NO	NO	NO	NO	NO
Firm FE	YES	YES	YES	YES	YES	YES	YES	YES
Model	OLS	OLS	OLS	OLS	OLS	OLS	OLS	OLS
Standard error	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level
Subsample	Pharmaceutical Firms subject to FDAAA							

This table presents robustness tests on regression results pertaining to the trend analysis of consequences before and after FDAAA regulatory change within the pharmaceutical firms in the treatment group over the 24-quarter (6-year) period. This subsample includes pharmaceutical firms whose clinical trial results are required to be disclosed following FDAAA requirement. *FDA MAUDE* is a binary variable equal to 1 if the firm was reported by a third party to FDA due to adverse event or product problem, 0 otherwise. *Ln Total FDA MAUDE* represents the log form of the number of FDA MAUDE complaint reports. *Adverse Event* is a binary variable equal to 1 if the firm was reported by a third party to FDA due to adverse event, 0 otherwise. *Ln Total Adverse Event* represents the log form of the number of FDA MAUDE complaint reports due to adverse event. *Product Problem* is a binary variable equal to 1 if the firm was reported by a third party to FDA due to product problem, 0 otherwise. *Ln Product Problem* represents the log form of the number of FDA MAUDE complaint reports due to product problem. *Recall* is a binary variable equal to 1 if the firm has made a recall, 0 otherwise. *Ln Total Recall* represents the log form of the number of total recalls including both drug and medical device recalls. Firm-level control variables are the same as those in the baseline model in Table 3. Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. Robust *t*-statistics are shown in parentheses. Standard errors are clustered at the firm level. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 10. Joint Effects of the FDAAA and its Associated Consequences on Bid-Ask Spread

Variables	(1) *Spread 100*	(2) *Spread 100*	(3) *Spread 100*	(4) *Spread 100*	(5) *Spread 100*	(6) *Spread 100*	(7) *Spread 100*	(8) *Spread 100*
FDA MAUDE	0.1022**							
	(2.20)							
FDA MAUDE X Post	**-0.3705*** **							
	(-5.35)							
Ln Total FDA MAUDE		-0.0501**						
		(-1.98)						
Ln Total FDA MAUDE X Post		**-0.0558*** **						
		(-4.68)						
Adverse Event			0.0993**					
			(2.00)					
Adverse Event X Post			**-0.3689*** **					
			(-5.09)					
Ln Total Adverse Event				-0.0154				
				(-0.57)				
Ln Total Adverse Event X Post				**-0.0704*** **				
				(-4.65)				
Product Problem					0.0835			
					(1.49)			
Product Problem X Post					**-0.3534*** **			
					(-4.98)			
Ln Total Product Problem						-0.0407		
						(-1.61)		
Ln Total Product Problem X Post						**-0.0562*** **		
						(-4.43)		
Recall							0.1063***	
							(2.85)	
Recall X Post							**-0.3814*** **	
							(-4.97)	
Ln Total Recall								0.0692**
								(2.60)
Ln Total Recall X Post								**-0.2468*** **
								(-4.71)
Constant	6.2287***	6.3107***	6.2456***	6.2934***	6.2535***	6.3128***	6.2779***	6.2944***
	(10.04)	(10.13)	(10.06)	(10.10)	(10.06)	(10.12)	(10.09)	(10.09)
Observations	2,608	2,608	2,608	2,608	2,608	2,608	2,608	2,608
Adjusted R-squared	0.6873	0.6868	0.6870	0.6859	0.6864	0.6863	0.6854	0.6852
Sample period	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each	Balanced 16 quarters / 8 quarters in the pre- and post- period each
Control variables	YES	YES	YES	YES	YES	YES	YES	YES
Year-Quarter FE	YES	YES	YES	YES	YES	YES	YES	YES
Firm FE	YES	YES	YES	YES	YES	YES	YES	YES
Model	OLS	OLS	OLS	OLS	OLS	OLS	OLS	OLS
Standard error	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level	Firm-level
Subsample	Pharmaceutical Firms subject to FDAAA							

This table presents regression results pertaining to the analysis of joint effects of the FDAAA and its associated consequences on bid-ask spread change within the pharmaceutical firms whose clinical trial results are required to be disclosed following the FDAAA. Please refer to Appendix for variable definitions. All continuous variables are winsorized at the 1st and 99th percentiles. Robust *t*-statistics are shown in parentheses. Standard errors are clustered at the firm level. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively.